



Clinical trial results:

A Phase 1 Trial of PF-03084014 in Patients With Advanced Solid Tumor Malignancy and T-Cell Acute Lymphoblastic Leukemia/Lymphoblastic Lymphoma

Summary

EudraCT number	2010-022036-36
Trial protocol	IT
Global end of trial date	22 November 2016

Results information

Result version number	v1 (current)
This version publication date	10 November 2017
First version publication date	10 November 2017

Trial information

Trial identification

Sponsor protocol code	A8641014
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00878189
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer ClinicalTrials.gov Call Center, 001 800781021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 May 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 January 2013
Global end of trial reached?	Yes
Global end of trial date	22 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this trial were:

1. To determine the maximum tolerated dose (MTD); and
2. To define the recommended phase 2 dose (RP2D) of PF-03084014 when administered twice daily (BID) for 21 days alone in patients with advanced malignancies.

Protection of trial subjects:

The study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 June 2009
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	Italy: 4
Country: Number of subjects enrolled	United States: 68
Worldwide total number of subjects	72
EEA total number of subjects	4

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)	51
From 65 to 84 years	21

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

This study originally planned to give PF-03084014 in combination with dexamethasone in subjects with solid tumors and with T-cell acute lymphoblastic leukemia and lymphoblastic lymphoma, including a drug-drug-interaction test of PF-03084014 and dexamethasone in solid tumor participants. But these parts were removed per protocol amendments.

Pre-assignment

Screening details:

This study was conducted in male or female with age greater than or equal to 16, and with advanced malignancies (encompassing solid tumors and refractory/ relapsed T-cell acute lymphoblastic leukemia and lymphoblastic lymphoma [T-ALL/ LBL]). Female who were pregnant or giving breast feeding had been excluded.

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	PF-03084014 20 mg BID in Solid Tumor Subjects

Arm description:

PF-03084014 20 mg was administered BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of pharmacokinetic (PK) assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03081014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 20 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 40 mg BID in Solid Tumor Subjects
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Arm description:

PF-03084014 40 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 40 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In

Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 80 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 80 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 80 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 100 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 100 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously..	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 100 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 130 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 130 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously..	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 130 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments.

purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 150 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 150 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 150 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 220 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 220 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 220 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 330 mg BID in Solid Tumor Subjects
Arm description: PF-03084014 330 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Arm type	Experimental
Investigational medicinal product name	PF-03084014
Investigational medicinal product code	PF-03084014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 330 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the

purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.

Arm title	PF-03084014 in T-ALL/LBL Subjects
Arm description: PF-03084014 150 mg was administered orally BID to subjects with T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (T-ALL/LBL) as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.	
Arm type	Experimental
Investigational medicinal product name	PF-03081014
Investigational medicinal product code	PF-03081014
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

PF-03084014 150 mg was administered orally BID to subjects with T-ALL/LBL as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Number of subjects in period 1	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects
Started	3	3	4
Completed	0	0	0
Not completed	3	3	4
Adverse event, serious fatal	-	1	-
Subject Refused Further Follow-up	-	-	4
Unspecified	3	2	-
Lost to follow-up	-	-	-
Objective progression or relapse	-	-	-

Number of subjects in period 1	PF-03084014 100 mg BID in Solid Tumor Subjects	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects
Started	8	4	23
Completed	0	0	0
Not completed	8	4	23
Adverse event, serious fatal	1	-	-
Subject Refused Further Follow-up	-	-	4
Unspecified	7	4	18
Lost to follow-up	-	-	1
Objective progression or relapse	-	-	-

Number of subjects in period 1	PF-03084014 220 mg BID in Solid	PF-03084014 330 mg BID in Solid	PF-03084014 in T- ALL/LBL Subjects
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	Tumor Subjects	Tumor Subjects	
Started	16	3	8
Completed	0	0	0
Not completed	16	3	8
Adverse event, serious fatal	-	-	1
Subject Refused Further Follow-up	-	-	-
Unspecified	15	3	4
Lost to follow-up	1	-	-
Objective progression or relapse	-	-	3

Baseline characteristics

Reporting groups

Reporting group title	Overall Study
Reporting group description: -	

Reporting group values	Overall Study	Total	
Number of subjects	72	72	
Age categorical			
Units: Subjects			
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	51	51	
From 65-84 years	21	21	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	52.9		
standard deviation	± 16.1	-	
Gender, Male/Female			
Units: Subjects			
Female	35	35	
Male	37	37	

Subject analysis sets

Subject analysis set title	PF-03084014 in T-ALL/LBL Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PF-03084014 150 mg was administered orally BID to subjects with T-ALL/LBL as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Subject analysis set title	PF-03084014 in Solid Tumor Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PF-03084014 20, 40, 80, 100, 130, 150, 220 and 330 mg was administered orally BID to subjects with advanced solid tumor malignancies as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Reporting group values	PF-03084014 in T-ALL/LBL Subjects	PF-03084014 in Solid Tumor Subjects	
Number of subjects	8	64	
Age categorical			
Units: Subjects			
Preterm newborn infants (gestational age < 37 wks)	0	0	

Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	8	43	
From 65-84 years	0	21	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	30.8	55.6	
standard deviation	± 9.0	± 14.7	
Gender, Male/Female			
Units: Subjects			
Female	2	33	
Male	6	31	

End points

End points reporting groups

Reporting group title	PF-03084014 20 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 20 mg was administered BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of pharmacokinetic (PK) assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 40 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 40 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 80 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 80 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 100 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 100 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously..	
Reporting group title	PF-03084014 130 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 130 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously..	
Reporting group title	PF-03084014 150 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 150 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 220 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 220 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 330 mg BID in Solid Tumor Subjects
Reporting group description: PF-03084014 330 mg was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, subjects with advanced solid tumor malignancies received PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was administered BID continuously.	
Reporting group title	PF-03084014 in T-ALL/LBL Subjects
Reporting group description: PF-03084014 150 mg was administered orally BID to subjects with T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma (T-ALL/LBL) as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.	

Subject analysis set title	PF-03084014 in T-ALL/LBL Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PF-03084014 150 mg was administered orally BID to subjects with T-ALL/LBL as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Subject analysis set title	PF-03084014 in Solid Tumor Subjects
Subject analysis set type	Sub-group analysis

Subject analysis set description:

PF-03084014 20, 40, 80, 100, 130, 150, 220 and 330 mg was administered orally BID to subjects with advanced solid tumor malignancies as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Primary: Number of Solid Tumor Subjects With First-Cycle Dose-Limiting Toxicity (DLT)

End point title	Number of Solid Tumor Subjects With First-Cycle Dose-Limiting Toxicity (DLT) ^{[1][2]}
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End point description:

Any DLT event attributable to PF-03084014 during Cycle 1: non-hematologic toxicities $\geq$ Grade 3 despite optimal care; treatment delay $\geq$ 7 days or unable to deliver at least 80% of planned dose due to treatment-related toxicities; Grade 4 neutropenia $>$ 7 days; febrile neutropenia; neutropenic infection; Grade $\geq$ 3 thrombocytopenia with bleeding. Analysis population included solid tumor subjects enrolled for dose-escalation who started treatment and who did not have first cycle major treatment deviations (including less than 80% of the planned dose of PF-03084014 in Cycle 1 for reasons other than treatment-related toxicities) were evaluable for DLTs.

End point type	Primary
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End point timeframe:

Baseline to the end of Cycle 1 (Week 4)

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: This endpoint only applies to solid tumor subjects.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint only applies to solid tumor subjects.

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	6
Units: subjects	0	0	0	1

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	6	2
Units: subjects	0	1	1	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of T-ALL/LBL Subjects With First-Cycle DLT

End point title	Number of T-ALL/LBL Subjects With First-Cycle DLT ^{[3][4]}
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End point description:

Any dose-limiting toxicity (DLT) attributable to PF-03084014 at 1st Cycle: non-hematologic toxicities $\geq$ Grade 3 despite optimal care; treatment delay ≥ 7 days; unable to deliver at least 80% of planned dose; absolute neutrophil count (ANC) < 1000 /microliter (uL), or platelet count $< 30,000$ /uL, or hemoglobin < 8 gram/deciliter (g/dL) in a bone marrow with $< 5\%$ blasts and no evidence of leukemia or abnormal dysplasia for > 42 days. Analysis population included T-ALL/LBL subjects enrolled for dose-escalation who started treatment and who did not have first cycle major treatment deviations (including less than 80% of the planned dose of PF-03084014 in Cycle 1 for reasons other than treatment-related toxicities) were evaluable for DLTs.

End point type	Primary
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End point timeframe:

Baseline to the end of Cycle 1 (Week 4)

Notes:

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

Justification: This endpoint only applies to T-ALL/LBL subjects

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint only applies to T-ALL/LBL subjects

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: subjects	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) (All Causality)

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) (All Causality)
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Treatment-emergent are events between first dose of study drug and up to 28 days after last dose that were absent before treatment or that worsened relative to pretreatment state. A serious adverse event (SAE) was any untoward medical occurrence at any dose that: Resulted in death, was life-threatening (immediate risk of death), required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), and resulted in congenital anomaly/birth defect. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to the end of study (28 days after last dose of study drug)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: subjects				
No. of Subjects With AEs	3	3	4	6
No. of Subjects With SAEs	1	1	2	4
No. of Subjects Discontinued PF-03084014	0	1	0	2
No. of Subjects Temp. Discontinued Treatment	1	1	2	1

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3
Units: subjects				
No. of Subjects With AEs	4	23	16	3
No. of Subjects With SAEs	2	8	7	1
No. of Subjects Discontinued PF-03084014	1	1	4	2
No. of Subjects Temp. Discontinued Treatment	1	9	5	1

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: subjects				
No. of Subjects With AEs	8			
No. of Subjects With SAEs	4			
No. of Subjects Discontinued PF-03084014	3			
No. of Subjects Temp. Discontinued Treatment	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With TEAEs (Treatment-Related)

End point title	Number of Subjects With TEAEs (Treatment-Related)
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug. Treatment-related events were those assessed by the investigator as related to study medication. An SAE was any untoward medical occurrence at any dose that: Resulted in death, was life-threatening (immediate risk of death), required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), and resulted in congenital anomaly/birth defect. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to the end of study (28 days after last dose of study drug).

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: subjects				
No. of Subjects With AEs	2	1	2	6
No. of Subjects With SAEs	0	0	0	1
No. of Subjects Discontinued PF-03084014	0	0	0	1
No. of Subjects Temp. Discontinued Treatment	0	0	0	0
No. of Subjects With Dose Reduction Due to AEs	0	0	0	0

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3
Units: subjects				
No. of Subjects With AEs	4	20	16	3
No. of Subjects With SAEs	1	0	1	0
No. of Subjects Discontinued PF-03084014	0	1	1	1
No. of Subjects Temp. Discontinued Treatment	1	7	4	1
No. of Subjects With Dose Reduction Due to AEs	1	4	3	1

End point values	PF-03084014 in T-ALL/LBL Subjects			
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Subject group type	Reporting group			
Number of subjects analysed	8			
Units: subjects				
No. of Subjects With AEs	5			
No. of Subjects With SAEs	1			
No. of Subjects Discontinued PF-03084014	0			
No. of Subjects Temp. Discontinued Treatment	0			
No. of Subjects With Dose Reduction Due to AEs	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) (All Causality) by maximum Common Terminology Criteria for Adverse Events (CTCAE) Grade

End point title	Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) (All Causality) by maximum Common Terminology Criteria for Adverse Events (CTCAE) Grade
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End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Treatment-emergent are events between first dose of study drug and up to 28 days after last dose that were absent before treatment or that worsened relative to pretreatment state. CTCAE version 3.0 was used for AE grading: Grade 1 mild AE; Grade 2 moderate AE; Grade 3 severe AE; Grade 4 life-threatening or disabling AE; Grade 5 death related to AE. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to the end of study (28 days after last dose of study drug)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: subjects				
Any AEs, Grade 1	0	0	1	0
Any AEs, Grade 2	2	1	0	1
Any AEs, Grade 3	1	1	2	2
Any AEs, Grade 4	0	0	1	2
Any AEs, Grade 5	0	1	0	1

End point values	PF-03084014 130 mg BID in	PF-03084014 150 mg BID in	PF-03084014 220 mg BID in	PF-03084014 330 mg BID in
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	Solid Tumor Subjects	Solid Tumor Subjects	Solid Tumor Subjects	Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3
Units: subjects				
Any AEs, Grade 1	0	1	1	0
Any AEs, Grade 2	2	8	3	0
Any AEs, Grade 3	2	12	9	2
Any AEs, Grade 4	0	2	1	1
Any AEs, Grade 5	0	0	2	0

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: subjects				
Any AEs, Grade 1	1			
Any AEs, Grade 2	1			
Any AEs, Grade 3	4			
Any AEs, Grade 4	1			
Any AEs, Grade 5	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with TEAEs (Treatment-Related) by Maximum CTCAE Grade

End point title	Number of Subjects with TEAEs (Treatment-Related) by Maximum CTCAE Grade
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End point description:

An AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. Treatment-related events were those assessed by the investigator as related to study medication. CTCAE version 3.0 was used for AE grading: Grade 1 mild AE; Grade 2 moderate AE; Grade 3 severe AE; Grade 4 life-threatening or disabling AE; Grade 5 death related to AE. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to the end of study (28 days after last dose of study drug)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: Subjects				
Any AEs, Grade 1	1	0	1	1
Any AEs, Grade 2	1	1	0	3
Any AEs, Grade 3	0	0	1	1
Any AEs, Grade 4	0	0	0	1
Any AEs, Grade 5	0	0	0	0
Missing or Unknown	0	0	0	0

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3
Units: Subjects				
Any AEs, Grade 1	1	6	2	0
Any AEs, Grade 2	2	6	4	1
Any AEs, Grade 3	1	8	10	2
Any AEs, Grade 4	0	0	0	0
Any AEs, Grade 5	0	0	0	0
Missing or Unknown	0	0	0	0

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Subjects				
Any AEs, Grade 1	3			
Any AEs, Grade 2	0			
Any AEs, Grade 3	1			
Any AEs, Grade 4	0			
Any AEs, Grade 5	0			
Missing or Unknown	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Potentially Clinical Significant Categorical

Changes From Baseline in Electrocardiogram (ECG) Findings in QTc Interval

End point title	Number of Subjects With Potentially Clinical Significant Categorical Changes From Baseline in Electrocardiogram (ECG) Findings in QTc Interval
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End point description:

Criteria for potentially important changes in ECG were defined as: maximum (max.) post-dose (post-baseline) time from electrocardiogram Q wave to the end of the T wave corresponding to electrical systole (QT interval) corrected for heart rate using Fridericia's formula (QTcF), or QT interval corrected for heart rate using Bazett's formula (QTcB): <450, 450-<480, 480-<500, and ≥500 msec. Maximum increase (inc.) from baseline in QTcF or QTcB: change (chg) <30, 30=<chg<60, and chg ≥60 msec. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to end of study treatment (Day 28).

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: subjects				
Max. QTcB interval <450	0	3	2	4
Max. QTcB interval 450-<480	3	0	1	3
Max. QTcB interval 480-<500	0	0	0	1
Max. QTcB interval ≥500	0	0	1	0
Max. QTcF interval <450	3	3	2	7
Max. QTcF interval 450-<480	0	0	1	0
Max. QTcF interval 480-<500	0	0	0	1
Max. QTcF interval ≥500	0	0	1	0
Max. QTcB interval inc. from baseline chg<30	1	2	1	7
Max. QTcB interval inc. from baseline 30=<chg<60	2	1	2	1
Max. QTcB interval inc. from baseline chg≥60	0	0	1	0
Max. QTcF interval inc. from baseline chg<30	3	2	1	7
Max. QTcF interval inc. from baseline 30=<chg<60	0	1	2	1
Max. QTcF interval inc. from baseline chg≥60	0	0	1	0

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3
Units: subjects				
Max. QTcB interval <450	2	11	5	2
Max. QTcB interval 450-<480	2	8	9	1

Max. QTcB interval 480-<500	0	4	0	0
Max. QTcB interval >=500	0	0	2	0
Max. QTcF interval <450	3	13	12	3
Max. QTcF interval 450-<480	1	9	2	0
Max. QTcF interval 480-<500	0	1	0	0
Max. QTcF interval >=500	0	0	2	0
Max. QTcB interval inc. from baseline chg<30	3	21	7	3
Max. QTcB interval inc. from baseline 30=<chg<60	1	2	7	0
Max. QTcB interval inc. from baseline chg>=60	0	0	2	0
Max. QTcF interval inc. from baseline chg<30	3	22	12	3
Max. QTcF interval inc. from baseline 30=<chg<60	1	1	2	0
Max. QTcF interval inc. from baseline chg>=60	0	0	2	0

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: subjects				
Max. QTcB interval <450	8			
Max. QTcB interval 450-<480	0			
Max. QTcB interval 480-<500	0			
Max. QTcB interval >=500	0			
Max. QTcF interval <450	8			
Max. QTcF interval 450-<480	0			
Max. QTcF interval 480-<500	0			
Max. QTcF interval >=500	0			
Max. QTcB interval inc. from baseline chg<30	7			
Max. QTcB interval inc. from baseline 30=<chg<60	1			
Max. QTcB interval inc. from baseline chg>=60	0			
Max. QTcF interval inc. from baseline chg<30	8			
Max. QTcF interval inc. from baseline 30=<chg<60	0			
Max. QTcF interval inc. from baseline chg>=60	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Laboratory Tests Abnormalities Meeting the

Criteria of Potential Clinical Concern (Hematology and Chemistries, All Cycles)

End point title	Number of Subjects With Laboratory Tests Abnormalities Meeting the Criteria of Potential Clinical Concern (Hematology and Chemistries, All Cycles)
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End point description:

Parameters analyzed included: White blood cell (WBC) count plus differential, absolute (Abs) neutrophil count, platelets, hemoglobin, sodium, potassium, bicarbonate, chloride, blood urea nitrogen, creatinine, glucose, uric acid, calcium, phosphate, magnesium, total protein, albumin, total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), partial prothrombin time/international normalized ratio (PTT/INR). Urinalysis: pH, specific gravity, protein, glucose, ketones, blood, leukocyte esterase, and nitrites. Pregnancy test: Serum or urine pregnancy test for women of childbearing potential. There were no changes in urine protein among the solid tumor and T-ALL/LBL subjects that were clinically significant. Clinical significance was judged by the investigator. Analysis population included all subjects who received at least 1 dose of study medication.

End point type	Secondary
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End point timeframe:

Baseline to the end of study (28 days after last dose of study drug).

End point values	PF-03084014 in T-ALL/LBL Subjects	PF-03084014 in Solid Tumor Subjects		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	64		
Units: subjects				
Hemoglobin	8	45		
Lymphocytes (abs)	8	40		
Neutrophils (abs)	5	4		
Platelets	6	13		
WBC	5	4		
ALT	4	22		
ALP	3	24		
AST	4	32		
Bicarbonate	1	15		
Bilirubin	2	10		
Creatinine	1	17		
Hypercalcaemia	0	2		
Hyperglycaemia	6	55		
Hyperkalaemia	0	4		
Hypermagnesaemia	0	1		
Hypernatraemia	0	4		
Hypoalbuminaemia	6	43		
Hypocalcaemia	6	18		
Hypoglycaemia	0	6		
Hypokalaemia	4	23		
Hypomagnesaemia	1	8		
Hyponatraemia	3	19		
Hypophosphataemia	4	54		

Statistical analyses

Secondary: Maximum Observed Serum Concentration (C_{max}) After a Single Dose on Cycle 1 Day 1

End point title	Maximum Observed Serum Concentration (C _{max}) After a Single Dose on Cycle 1 Day 1
End point description: C _{max} was the maximum observed serum concentration. Analysis population included all treated subjects who had at least 1 of the pharmacokinetic (PK) parameters of interest. N=number of subjects evaluable for this endpoint	
End point type	Secondary
End point timeframe: Cycle 1 Day 1 (predose and 0.5, 1, 2, 4, and 10 hours [hr] postdose)	

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: nanogram/milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	163 (± 62)	368 (± 48)	230 (± 193)	691 (± 37)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	22	16	3
Units: nanogram/milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	536 (± 72)	943 (± 100)	861 (± 63)	1892 (± 54)

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: nanogram/milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	1604 (± 85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Cmax (Tmax) After a Single Dose on Cycle 1 Day 1

End point title	Time to Reach Cmax (Tmax) After a Single Dose on Cycle 1 Day 1
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End point description:

Tmax was the time to reach maximum serum concentration (Cmax). Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, and 10 hr post-dose)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: hr				
median (full range (min-max))	1.0 (0.9 to 1.0)	1.0 (1.0 to 1.3)	2.0 (1.0 to 8.0)	1.0 (1.0 to 2.0)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	22	16	3
Units: hr				
median (full range (min-max))	2.5 (1.0 to 4.0)	1.1 (0.5 to 4.1)	2.0 (1.0 to 4.1)	1.2 (1.0 to 2.0)

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: hr				
median (full range (min-max))	1.1 (0.9 to 4.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Time-Concentration Curve From Time 0 to the Dosing

Interval (AUCtau) After a Single Dose on Cycle 1 Day 1

End point title	Area Under the Time-Concentration Curve From Time 0 to the Dosing Interval (AUCtau) After a Single Dose on Cycle 1 Day 1
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End point description:

AUCtau was area under the serum concentration-time profile from time 0 to tau (dosing interval).99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, and 10 hr post-dose)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	7
Units: nanogram*hour/milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	409 (± 83)	1329 (± 87)	1649 (± 98)	2204 (± 37)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	21	16	2 ^[5]
Units: nanogram*hour/milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	2924 (± 81)	3677 (± 86)	3593 (± 58)	8014 (± 99999)

Notes:

[5] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: nanogram*hour/milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	6412 (± 80)			

Statistical analyses

Secondary: Cmax After Multiple Dose on Cycle 1 Day 21

End point title	Cmax After Multiple Dose on Cycle 1 Day 21 ^[6]
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End point description:

Cmax was the maximum observed serum concentration. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[7]	2 ^[8]	3	5
Units: ng/mL				
geometric mean (geometric coefficient of variation)	64.5 (± 99999)	381 (± 99999)	313 (± 29)	867 (± 44)

Notes:

[7] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[8] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)	421 (± 130)	1246 (± 79)	1894 (± 76)	1828 (± 42)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Cmax (Tmax) after multiple dose on Cycle 1 Day 21

End point title	Time to Reach Cmax (Tmax) after multiple dose on Cycle 1 Day 21 ^[9]
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End point description:

Tmax was the time to reach maximum serum concentration (Cmax). Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for

subjects who were considered to be dose compliant.

End point type	Secondary
End point timeframe:	
Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)	

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	5
Units: hr				
median (full range (min-max))	1.1 (1.0 to 1.1)	1.0 (1.0 to 1.0)	1.0 (1.0 to 4.0)	1.1 (1.0 to 2.7)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: hr				
median (full range (min-max))	3.7 (1.0 to 8.0)	1.1 (1.0 to 4.0)	1.0 (0.5 to 2.0)	1.6 (1.0 to 2.0)

Statistical analyses

No statistical analyses for this end point

Secondary: AUCtau After Multiple Dose on Cycle 1 Day 21

End point title	AUCtau After Multiple Dose on Cycle 1 Day 21 ^[10]
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End point description:

AUCtau was area under the serum concentration-time profile from time 0 to tau (dosing interval). 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[11]	2 ^[12]	3	5
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	309 (± 99999)	2521 (± 99999)	1572 (± 42)	4741 (± 70)

Notes:

[11] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[12] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	3155 (± 59)	6430 (± 89)	10520 (± 89)	9161 (± 30)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution (V_z/F) on Cycle 1 Day 21

End point title	Apparent Volume of Distribution (V _z /F) on Cycle 1 Day 21 ^[13]
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End point description:

Volume of distribution was defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired concentration of a drug. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[14]	2 ^[15]	2 ^[16]	5
Units: liter (L)				
geometric mean (geometric coefficient of variation)	2810 (± 99999)	516 (± 99999)	3353 (± 99999)	986 (± 52)

Notes:

[14] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[15] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[16] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	3
Units: liter (L)				
geometric mean (geometric coefficient of variation)	2048 (± 49)	801 (± 144)	852 (± 120)	424 (± 61)

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Decay Half-Life (t_{1/2}) After Multiple Dose on Cycle 1 Day 21

End point title	Serum Decay Half-Life (t _{1/2}) After Multiple Dose on Cycle 1 Day 21 ^[17]
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End point description:

Serum decay half-life is the time measured for the serum concentration to decrease by one half. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[18]	2 ^[19]	2 ^[20]	5
Units: hr				
arithmetic mean (standard deviation)	30.3 (± 99999)	22.6 (± 99999)	38.6 (± 99999)	34.2 (± 11.7)

Notes:

[18] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[19] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[20] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	3
Units: hr				
arithmetic mean (standard deviation)	34.7 (± 5.3)	25.3 (± 9.2)	29.3 (± 9.3)	18.0 (± 3.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Oral Clearance (CL/F) on Cycle 1 Day 21

End point title	Apparent Oral Clearance (CL/F) on Cycle 1 Day 21 ^[21]
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End point description:

Clearance of a drug is a measure of the rate at which a drug is metabolized or eliminated by normal biological processes. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[22]	2 ^[23]	3	5
Units: liter/hour (L/hr)				
geometric mean (geometric coefficient of variation)	64.8 (± 99999)	15.9 (± 99999)	50.9 (± 42)	21.1 (± 70)

Notes:

[22] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[23] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: liter/hour (L/hr)				
geometric mean (geometric coefficient of variation)	41.2 (± 59)	23.4 (± 88)	20.9 (± 89)	16.4 (± 30)

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Observed Serum Concentration (Cmin) After Multiple Dose on Cycle 1 Day 21

End point title	Minimum Observed Serum Concentration (Cmin) After Multiple Dose on Cycle 1 Day 21 ^[24]
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End point description:

Cmin was the minimum observed serum concentration. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (predose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr postdose)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[25]	2 ^[26]	3	5
Units: ng/mL				
geometric mean (geometric coefficient of variation)	10.7 (± 99999)	126 (± 99999)	59.2 (± 103)	232 (± 118)

Notes:

[25] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[26] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)	206 (± 40)	266 (± 102)	469 (± 118)	420 (± 81)

Statistical analyses

No statistical analyses for this end point

Secondary: Average Serum Concentration (Cavg) at Steady State on Cycle 1 Day 21

End point title	Average Serum Concentration (Cavg) at Steady State on Cycle 1 Day 21 ^[27]
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End point description:

Cavg was the average serum concentration at steady state. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (predose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr postdose)

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[28]	2 ^[29]	3	5
Units: ng/mL				
geometric mean (geometric coefficient of variation)	25.7 (± 99999)	210 (± 99999)	131 (± 42)	395 (± 69)

Notes:

[28] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

[29] - Geometric %CV was NE when No. of subjects analyzed is <3, hence data was not calculated.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)	263 (± 59)	536 (± 89)	877 (± 89)	763 (± 30)

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation ratio (Rac) on Cycle 1 Day 21

End point title	Accumulation ratio (Rac) on Cycle 1 Day 21 ^[30]
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End point description:

Accumulation was calculated as AUCtau at steady state (Cycle 1 Day 21) divided by AUCtau after a single dose on Cycle 1 Day 1. 99999 signifies data not estimable. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (predose and 0.5, 1, 2, 4, and 10 hr postdose), Cycle 1 Day 21 (predose and 0.5, 1, 2,

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	2	5
Units: ratio				
median (full range (min-max))	1.18 (0.72 to 1.63)	1.60 (1.45 to 1.74)	1.36 (0.93 to 1.79)	2.49 (1.23 to 2.86)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	1 ^[31]
Units: ratio				
median (full range (min-max))	1.98 (1.81 to 2.15)	2.29 (0.95 to 4.90)	2.84 (1.14 to 5.80)	0.97 (00000 to 99999)

Notes:

[31] - Unable to calculate median and range as only 1 subject provided value.

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized AUCtau [AUCtau(dn)] in the Fasted State for Solid Tumor Subjects

End point title	Dose-normalized AUCtau [AUCtau(dn)] in the Fasted State for Solid Tumor Subjects
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End point description:

AUCtau(dn) was calculated by area under the serum concentration-time profile from time 0 to tau (dosing interval) (AUCtau) divided by administered dose. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (predose and 0.5, 1, 2, 4, 10 and 24 hr post-dose) or Cycle 2 Day 1 (predose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

End point values	PF-03084014 in Solid Tumor Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	23.71 (± 115)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized AUCtau [AUCtau(dn)] in the Fed State for Solid Tumor Subjects

End point title	Dose-normalized AUCtau [AUCtau(dn)] in the Fed State for Solid Tumor Subjects
End point description: AUCtau(dn) was calculated by area under the serum concentration-time profile from time 0 to tau (dosing interval) (AUCtau) divided by administered dose. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.	
End point type	Secondary
End point timeframe: Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)	

End point values	PF-03084014 in Solid Tumor Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	11			
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	22.54 (± 67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized Cmax [Cmax(dn)] in the Fasted State for Solid Tumor Subjects

End point title	Dose-normalized Cmax [Cmax(dn)] in the Fasted State for Solid Tumor Subjects
End point description: Cmax(dn) was calculated by maximum observed serum concentration (Cmax) divided by administered dose. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.	

End point type	Secondary
End point timeframe:	
Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)	

End point values	PF-03084014 in Solid Tumor Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: (ng/mL)/milligram (ng/mL)/mg				
geometric mean (geometric coefficient of variation)	6.56 ($\pm$ 106)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized C_{max}(dn) in the Fed State for Solid Tumor Subjects

End point title	Dose-normalized C _{max} (dn) in the Fed State for Solid Tumor Subjects
End point description:	
C _{max} (dn) was calculated by maximum observed serum concentration (C _{max}) divided by administered dose. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.	
End point type	Secondary
End point timeframe:	
Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose) or Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose) and Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)	

End point values	PF-03084014 in Solid Tumor Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: (ng/mL)/mg				
geometric mean (geometric coefficient of variation)	5.22 ($\pm$ 64)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Solid Tumor Subjects With Objective Response (OR)

End point title	Percentage of Solid Tumor Subjects With Objective Response (OR) ^[32]
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End point description:

OR was defined as confirmed complete response (CR) or confirmed partial response (PR) according to Response Evaluation Criteria in Solid Tumors (RECIST) (version 1.0). Confirmed CR defined as disappearance of all target lesions. Confirmed PR defined as $\geq 30\%$ decrease in sum of the longest dimensions (LD) of the target lesions taking as a reference the baseline sum LD according to RECIST. Confirmed responses are those that persist on repeat imaging study ≥ 4 weeks after initial documentation of response.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (plus [+] or minus [-] 5 days) of every odd cycle or as clinically indicated, up to Cycle 9; afterwards assessed on Day 1 (+ or -5 days) every 4 cycles

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to solid tumor subjects only

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	5
Units: percentage of subjects				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	0 (0.0 to 70.8)	66.7 (9.4 to 99.2)	0 (0.0 to 52.2)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	18	10	1
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 70.8)	5.6 (0.1 to 27.3)	10.0 (0.3 to 44.5)	100 (2.5 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP) for Solid Tumor Subjects

End point title	Time to Progression (TTP) for Solid Tumor Subjects ^[33]
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End point description:

Time from Cycle 1 Day 1 to first documentation of disease progression. Progression was defined as per RECIST version 1.0, as a 20% increase in the sum of the longest diameter of target lesions, or target lesions over nadir, unequivocal progression of non-target disease, or the appearance of new lesions. TTP (months) was calculated as (first event date minus the date of first dose of study medication plus 1) divided by 30. 99999 signifies data not estimable.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or - 5 days) of every odd cycle or as clinically indicated, up to Cycle 9; afterwards assessed on Day 1 (+ or -5 days) every 4 cycles

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to solid tumor subjects only

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[34]	3	4 ^[35]	8 ^[36]
Units: months				
median (confidence interval 95%)	99999 (0.8 to 99999)	1.2 (1.0 to 2.8)	99999 (1.7 to 99999)	3.1 (1.0 to 99999)

Notes:

[34] - As 2 subjects were censored and only 1 subject was evaluable

[35] - Unable to calculate as 3 subjects were censored and only 1 subject was evaluable

[36] - The upper 95% confidence limit can not be calculated due to limited number of subjects

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3 ^[37]
Units: months				
median (confidence interval 95%)	4.3 (1.6 to 19.5)	1.6 (1.4 to 6.0)	1.5 (1.1 to 4.2)	99999 (99999 to 99999)

Notes:

[37] - Unable to calculate as all 3 subjects were censored

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DR) for Solid Tumor Subjects

End point title	Duration of Response (DR) for Solid Tumor Subjects ^[38]
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End point description:

Time from the first documentation of OR to objective disease progression or death due to any cause. DR was only calculated for subjects with an OR. DR (months) was calculated as (date of first documentation of objective progression or death minus date of first documentation of PR or CR plus 1) divided by 30. 99999 signifies data not estimable.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or -5 days) of every odd cycle or as clinically indicated, up to Cycle 9. Afterwards, assessed on Day 1 (+ or -5 days) every 4 cycles.

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to solid tumor subjects only

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[39]	2 ^[40]	1 ^[41]	1 ^[42]
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

Notes:

[39] - Unable to calculate as the subject was censored.

[40] - Unable to calculate as the subject was censored.

[41] - Unable to calculate as the subject was censored.

[42] - Unable to calculate as the subject was censored.

End point values	PF-03084014 330 mg BID in Solid Tumor Subjects			
Subject group type	Reporting group			
Number of subjects analysed	1 ^[43]			
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)			

Notes:

[43] - Unable to calculate as the subject was censored.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) for Solid Tumor Subjects

End point title	Progression-Free Survival (PFS) for Solid Tumor Subjects ^[44]
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End point description:

PFS was defined as the time from Cycle 1 Day 1 to date of first documentation of progression or death due to any cause. Progression was defined as per RECIST version 1.0, as a 20% increase in the sum of the longest diameter of target lesions, or target lesions over nadir, unequivocal progression of non-target disease, or the appearance of new lesions. PFS (months) was calculated as (the first event date minus the date of first dose of study medication plus 1) divided by 30. 99999 signifies data not applicable.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or - 5 days) of every odd cycle or as clinically indicated, up to Cycle 9; afterwards assessed on Day 1 (+ or -5 days) every 4 cycles

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to solid tumor subjects only

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[45]	3	4 ^[46]	8 ^[47]
Units: months				
median (confidence interval 95%)	99999 (0.8 to 99999)	1.2 (1.0 to 2.8)	99999 (1.7 to 99999)	2.3 (0.4 to 99999)

Notes:

[45] - Unable to calculate as 2 subjects were censored and only 1 subject was evaluable.

[46] - Unable to calculate as 3 subjects were censored and only 1 subject was evaluable.

[47] - The upper 95% confidence limit can not be determined due to limited number of subjects with PFS.

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	23	16	3 ^[48]
Units: months				
median (confidence interval 95%)	4.3 (1.6 to 19.5)	1.6 (1.4 to 6.0)	1.5 (1.1 to 4.2)	99999 (99999 to 99999)

Notes:

[48] - Unable to calculate as all 3 subjects were censored.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of T-ALL/LBL subjects with OR

End point title	Percentage of T-ALL/LBL subjects with OR ^[49]
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End point description:

OR was adapted from International Working Group Response Criteria for Acute Myeloid Leukemia (AML). The response categories of interest were CR, complete response with incomplete hematopoietic recovery (CRi), and PR. CR: ANC >1500/microliter (uL), no circulating blasts. Platelets >100,000/uL, <5% marrow blast cells, no extramedullary disease, bone marrow cellularity >20% with tri-lineage hematopoiesis and <5% marrow blast cells, none of which were neoplastic; CRi: same as CR but ANC may be >1500/uL or platelet count >100,000/uL, no requirement on bone marrow cellularity; PR: same as CR but bone marrow with >= 50% reduction of leukemia blast cells and an absolute blast count between 5% and 25%.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or - 5 days) of every odd cycle or as clinically indicated, up to Cycle 9.

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to T-ALL/LBL subjects only

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: percentage of subjects				
number (confidence interval 95%)	12.5 (0.3 to 52.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Relapse Free Survival (RFS) for T-ALL/LBL subjects

End point title	Relapse Free Survival (RFS) for T-ALL/LBL subjects ^[50]
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End point description:

The RFS of CR was defined as the time from the date of first attaining CR to the date of relapse or death from any cause, whichever occurred first. Similarly, the RFS of CR + CRi (or RFS of CR + CRi + partial response [PR]) was defined as the time from the date of first attaining CR + CRi (or CR + CRi + PR) to the date of relapse or death from any cause, whichever occurred first.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or - 5 days) of every odd cycle or as clinically indicated, up to Cycle 9.

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to T-ALL/LBL subjects only

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[51]			
Units: months				
median (confidence interval 95%)	(to)			

Notes:

[51] - Data not analyzed due to halting of T-ALL/LBL subject enrollment and the limited No. of subjects.

Statistical analyses

No statistical analyses for this end point

Secondary: Peripheral Blast Count Reduction (PBR) for T-ALL/LBL Subjects

End point title	Peripheral Blast Count Reduction (PBR) for T-ALL/LBL
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End point description:

PBR was the maximum percentage of peripheral blast count reduction for each subject who received at least one dose of study medication. PBR was derived by the Sponsor from percentage of peripheral blood Blast Count reported by sites.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or - 5 days) of every odd cycle or as clinically indicated, up to Cycle 9.

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to T-ALL/LBL subjects only

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[53]			
Units: percentage of PBR				
number (confidence interval 95%)	(to)			

Notes:

[53] - Data not analyzed due to halting of T-ALL/LBL subject enrollment and the limited No. of subjects.

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in Expression Levels of Notch 1 Target Genes in Tumor Biopsies for Solid Tumor Subjects: Hes4 Gene Expression Levels on Cycle 1 Day 21 Relative to That at Baseline

End point title	Changes in Expression Levels of Notch 1 Target Genes in Tumor Biopsies for Solid Tumor Subjects: Hes4 Gene Expression Levels on Cycle 1 Day 21 Relative to That at Baseline ^[54]
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End point description:

Gene expression analysis in tumor biopsies was done using cDNA prepared from ribonucleic acid (RNA) extracted from tumor biopsies. Gene expression was measured by custom Taqman low density array (TLDA) cards run on Applied Biosystems 7900HT Fast Real-Time polymerase chain reaction (PCR) system. Changes from baseline were calculated as ratios to baseline. Only Hes4 gene showed consistent down modulation across dosing cohorts (150 mg and 220 mg BID) and therefore results were reported for Hes4 only.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 1 Day 21 (-5 days)

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: ratio				
arithmetic mean (standard deviation)	0.9 (± 0.57)	0.5 (± 0.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Changes From Baseline in Expression Levels of Notch 1 Target Genes in Peripheral Blood for T-ALL/LBL Subjects: Hes4 Gene Expression Levels on Cycle 1 Day 8, Cycle 1 Day 15, Cycle 1 Day 21 Relative to That at Baseline

End point title	Changes From Baseline in Expression Levels of Notch 1 Target Genes in Peripheral Blood for T-ALL/LBL Subjects: Hes4 Gene Expression Levels on Cycle 1 Day 8, Cycle 1 Day 15, Cycle 1 Day 21 Relative to That at Baseline
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End point description:

RNA was extracted from peripheral blood and used as a template to synthesize complementary deoxyribonucleic acid (cDNA). Gene expression in cDNA was measured by custom Taqman low density array (TLDA) cards run on Applied Biosystems 7900HT Fast Real-Time PCR system. Changes from baseline were calculated as ratios to baseline. Results were reported Only for Hes4 as this was the only gene to show consistent down modulation across dosing cohorts (150 mg and 220 mg).

End point type	Secondary
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End point timeframe:

Baseline (morning), Cycle 1 Days 8, 15 and 21 (morning, matched with the first PK sample of the particular day), Cycle 1 Day 21 (24, 48, and 120 hr postdose) and at end of treatment (EoT)

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8 ^[55]			
Units: ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 8, n=7	0.7 (± 0.65)			
Cycle 1 Day 15, n=4	0.3 (± 0.41)			
Cycle 1 Day 21, n=4	0.4 (± 0.27)			
EOT, n=1	2.0 (± 99999)			

Notes:

[55] - Data for standard deviation at EOT was not estimable since only 1 participant was analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in Expression Levels of Notch 1 Target Genes in Peripheral Blood for Solid Tumor Subjects: Hairy and Enhancer of Split-4 (Hes4) Gene Expression Level on Cycle 1 Day 8 and Cycle 1 Day 21 Relative to That at Baseline

End point title	Changes in Expression Levels of Notch 1 Target Genes in Peripheral Blood for Solid Tumor Subjects: Hairy and Enhancer of Split-4 (Hes4) Gene Expression Level on Cycle 1 Day 8 and
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End point description:

RNA was extracted from peripheral blood and used as a template to synthesize DNA. Gene expression in cDNA was measured by custom TLDA cards run on Applied Biosystems 7900HT Fast Real-Time PCR system. Changes from baseline were calculated as ratios to baseline. Results were reported Only for Hes4 as this was the only gene to show consistent down modulation across dosing cohorts (150 mg and 220 mg).

End point type	Secondary
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End point timeframe:

Baseline (morning), Cycle 1 Days 8 and 21 (predose)

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 8, n=11, 7	0.3 (± 0.24)	0.1 (± 0.14)		
Cycle 1 Day 21, n=6, 5	0.3 (± 0.33)	0.0 (± 0.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: Changes From Baseline in Notch Intracellular Domain (NICD) Levels in Peripheral Blood for T-ALL/LBL Subjects

End point title	Changes From Baseline in Notch Intracellular Domain (NICD) Levels in Peripheral Blood for T-ALL/LBL Subjects ^[57]
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End point description:

NICD was measured in peripheral blood mononuclear cell (PBMC) pellets using a validated enzyme-linked immunosorbent assay (ELISA). LOQ is the lower limit of quantitation.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 1 Days 8 and 15 (predose AM), Cycle 1 Day 21 (predose AM and 24, 48 and 120 hr postdose) and EOT

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to T-ALL/LBL subjects only

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[58]			
Units: optical density				
arithmetic mean (standard deviation)	()			

Notes:

[58] - As NICD levels fell below the LOQ of the assay in most cases, No data were reported.

Statistical analyses

No statistical analyses for this end point

Secondary: Changes From Baseline in Notch Intracellular Domain (NICD) Levels in Bone Marrow for T-ALL/LBL Subjects

End point title	Changes From Baseline in Notch Intracellular Domain (NICD) Levels in Bone Marrow for T-ALL/LBL Subjects ^[59]
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End point description:

NICD was to be measured in bone marrow mononuclear cell (BMMC) cell pellets using a validated ELISA.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 and Cycles 2 Day 1

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to T-ALL/LBL subjects only

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[60]			
Units: microgram/milliliter				
arithmetic mean (standard deviation)	()			

Notes:

[60] - No. of bone marrow samples received was insufficient and analyses were not mandatory per protocol.

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized Cmax [Cmax (dn)] After a Single Dose on Cycle 1 Day 1

End point title	Dose-normalized Cmax [Cmax (dn)] After a Single Dose on Cycle 1 Day 1
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End point description:

Cmax(dn) was calculated by maximum observed serum concentration (Cmax) divided by administered dose. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, and 10 hr post-dose)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	8
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	8.1 (± 63)	9.2 (± 48)	2.9 (± 193)	6.9 (± 37)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	22	16	3
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	4.1 (± 72)	6.3 (± 100)	3.9 (± 63)	5.7 (± 54)

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	10.7 (± 85)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized AUCtau [AUCtau (dn)] After a single dose on Cycle 1 Day 1

End point title	Dose-normalized AUCtau [AUCtau (dn)] After a single dose on Cycle 1 Day 1
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End point description:

AUCtau (dn) was calculated by area under the serum concentration-time profile from time 0 to tau (dosing interval) (AUCtau) divided by administered dose. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint. 99999 signifies data that are not estimable.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, and 10 hr post-dose)

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	7
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	20.4 (± 83)	33.2 (± 87)	20.6 (± 98)	22.0 (± 37)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	21	16	2
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	22.5 (± 81)	24.5 (± 86)	16.3 (± 58)	24.3 (± 99999)

End point values	PF-03084014 in T-ALL/LBL Subjects			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	42.7 (± 80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized AUCtau [AUCtau (dn)] After Multiple Dose on Cycle 1 Day 21

End point title	Dose-normalized AUCtau [AUCtau (dn)] After Multiple Dose on Cycle 1 Day 21 ^[61]
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End point description:

AUCtau (dn) was calculated by area under the serum concentration-time profile from time 0 to tau (dosing interval) (AUCtau) divided by administered dose. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	5
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	15.4 (± 99999)	63.0 (± 99999)	19.7 (± 41)	47.4 (± 70)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: (ng*hr/mL)/mg				
geometric mean (geometric coefficient of variation)	24.3 (± 59)	42.9 (± 88)	47.9 (± 89)	61.1 (± 30)

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized Cmax [Cmax (dn)] After Multiple Dose on Cycle 1 Day 21

End point title	Dose-normalized Cmax [Cmax (dn)] After Multiple Dose on Cycle 1 Day 21 ^[62]
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End point description:

Cmax(dn) was calculated by maximum observed serum concentration (Cmax) divided by administered dose. 99999 represents data not estimable (NE) when the number (No.) of subjects analyzed is less than (<) 3. Analysis population included all subjects who had at least 6 days of uninterrupted dosing prior to the Cycle 1 Day 21 PK assessment. The 6-day duration was chosen based on the observed terminal half-life of PF-03084014. N=number of subjects evaluable for this endpoint. Cycle 1 Day 21 PK parameter summaries are presented only for subjects who were considered to be dose compliant.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 21 (pre-dose and 0.5, 1, 2, 4, 10, 24, 48, 96 and 120 hr post-dose)

Notes:

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No data was available for the 330 mg BID in solid tumor subjects arm

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	5
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	3.2 (± 99999)	9.6 (± 99999)	3.9 (± 29)	8.7 (± 44)

End point values	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	12	8	4
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	3.2 (± 130)	8.3 (± 79)	8.5 (± 76)	12.2 (± 42)

Statistical analyses

No statistical analyses for this end point

Secondary: AUCtau in the Fasted State for Solid Tumor Subjects

End point title	AUCtau in the Fasted State for Solid Tumor Subjects ^[63]
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End point description:

AUCtau was area under the serum concentration-time profile from time 0 to tau (dosing interval). Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr postdose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to only solid tumor subjects who participated in food effects study

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	4		
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	2547 (± 101)	9353 (± 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUCtau in the Fed State for Solid Tumor Subjects

End point title	AUCtau in the Fed State for Solid Tumor Subjects ^[64]
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End point description:

AUCtau was area under the serum concentration-time profile from time 0 to tau (dosing interval). Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr postdose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to only solid tumor subjects who participated in food effects study

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	4		
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	3163 (± 83)	5573 (± 39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in the Fasted State for Solid Tumor Subjects

End point title	Cmax in the Fasted State for Solid Tumor Subjects ^[65]
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End point description:

Cmax was the maximum observed serum concentration. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr postdose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to only solid tumor subjects who participated in food effects study

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	795.1 (± 104)	2334 (± 93)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in the Fed State for Solid Tumor Subjects

End point title	Cmax in the Fed State for Solid Tumor Subjects ^[66]
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End point description:

Cmax was the maximum observed serum concentration. Analysis population included solid tumor subjects who were enrolled in the food-effect sub-study, were treated and had evaluable PK data under both fed and fasted states.

End point type	Secondary
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End point timeframe:

Cycle 1 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr postdose) or Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to only solid tumor subjects who participated in food effects study

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	862.3 (± 74)	924.4 (± 40)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUCtau on Cycle 2 Day 1

End point title	AUCtau on Cycle 2 Day 1 ^[67]
End point description: AUCtau was area under the serum concentration-time profile from time 0 to tau (dosing interval). Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.	
End point type	Secondary
End point timeframe: Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)	

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	4		
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	2784 (± 80)	11870 (± 57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized AUCtau [AUCtau (dn)] on Cycle 2 Day 1

End point title	Dose-normalized AUCtau [AUCtau (dn)] on Cycle 2 Day 1 ^[68]
End point description: AUCtau(dn) was calculated by area under the serum concentration-time profile from time 0 to tau (dosing interval) (AUCtau) divided by administered dose. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.	
End point type	Secondary
End point timeframe: Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)	

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	4		
Units: ng*hr/mL/mg				
geometric mean (geometric coefficient of variation)	18.6 (± 80)	54.0 (± 57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax on Cycle 2 Day 1

End point title	Cmax on Cycle 2 Day 1 ^[69]
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End point description:

Cmax was the maximum observed serum concentration. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	834.6 (± 76)	2640 (± 63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Dose-normalized Cmax [Cmax (dn)] on Cycle 2 Day 1

End point title	Dose-normalized Cmax [Cmax (dn)] on Cycle 2 Day 1 ^[70]
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End point description:

Cmax(dn) was calculated by maximum observed serum concentration (Cmax) divided by administered dose. Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	5.6 (± 76)	12.0 (± 63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax on Cycle 2 Day 1

End point title	Tmax on Cycle 2 Day 1 ^[71]
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End point description:

Tmax was the time to reach maximum serum concentration (Cmax). Analysis population included all treated subjects who had at least 1 of the PK parameters of interest. N=number of subjects evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Cycle 2 Day 1 (pre-dose and 0.5, 1, 2, 4, 10 and 24 hr post-dose)

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to 150 mg BID and 220 mg BID in solid tumor subjects arms only

End point values	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	4		
Units: hr				
median (full range (min-max))	2.00 (1.00 to 4.03)	1.53 (0.98 to 4.00)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Time to Response (TTR) for Solid Tumor Subjects

End point title	Time to Response (TTR) for Solid Tumor Subjects ^[72]
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End point description:

TTR was only defined for subjects with an OR. TTR (months) was calculated as (date of first documentation of PR or CR minus date of first dose of study medication plus 1) divided by 30. 99999 signifies data not estimable.

End point type	Post-hoc
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End point timeframe:

Baseline, Cycle 2 Day 1, Cycle 3 Day 1 and then Day 1 (+ or -5 days) of every odd cycle or as clinically indicated, up to Cycle 9. Afterwards, assessed on Day 1 (+ or -5 days) every 4 cycles.

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint applies to solid tumor subjects only

End point values	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects	PF-03084014 220 mg BID in Solid Tumor Subjects
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[73]	2	1 ^[74]	1 ^[75]
Units: months				
median (confidence interval 95%)	11.2 (00000 to 99999)	19.4 (8.5 to 30.4)	2.9 (00000 to 99999)	10.1 (00000 to 99999)

Notes:

[73] - Data for upper and lower limit of 95% CI were not estimable since only 1 subject was analyzed.

[74] - Data for upper and lower limit of 95% CI were not estimable since only 1 subject was analyzed.

[75] - Data for upper and lower limit of 95% CI were not estimable since only 1 subject was analyzed.

End point values	PF-03084014 330 mg BID in Solid Tumor Subjects			
Subject group type	Reporting group			
Number of subjects analysed	1 ^[76]			
Units: months				
median (confidence interval 95%)	5.9 (00000 to 99999)			

Notes:

[76] - Data for upper and lower limit of 95% CI were not estimable since only 1 subject was analyzed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Two (2) years

Adverse event reporting additional description:

Same event may appear as AE and SAE, what is presented are distinct events.

Event may be categorized as serious in 1 subject and non-serious in another

subject or 1 subject may have experienced both serious and non-serious

event. The safety analysis set includes all enrolled subjects who receive at least

1 dose of study medication.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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Reporting groups

Reporting group title	PF-03084014 40 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 20 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally twice daily (BID), beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of pharmacokinetic (PK) assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 100 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 80 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 130 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 150 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 220 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose

was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 330 mg BID in Solid Tumor Subjects
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Reporting group description:

PF-03084014 was administered orally BID, beginning on Day 1 of each cycle, for 21 days. In Cycle 1 only, patients were to receive PF-03084014 BID for 21 days (on Cycle 1 Day 21 only the morning dose was to be administered) followed by 7 days' off-treatment for the purpose of PK assessments. In Cycle 2 and beyond, PF-03084014 was to be administered BID continuously.

Reporting group title	PF-03084014 in T-ALL/LBL Subjects
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Reporting group description:

PF-03084014 150 mg was administered orally BID to subjects with T-ALL/LBL as single agent for 21 days per cycle continuously (except for Cycle 1). On Cycle 1 Day 21, only the morning dose was administered, followed by a 7-day washout interval.

Serious adverse events	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	4 / 8 (50.00%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Investigations			
GRAM POSITIVE COCCI			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Gamma-glutamyltransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Arterial injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Joint dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
General disorders and administration site conditions			

Disease progression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (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

Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Lung infiltration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Product issues			
Device dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 4 (50.00%)	8 / 23 (34.78%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Investigations			
GRAM POSITIVE COCCI			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Neutrophil count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Injury, poisoning and procedural complications			
Arterial injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Hip fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Joint dislocation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (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

General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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 / 1
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (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 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Diarrhoea			

subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Lung infiltration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (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
Mental status changes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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
Product issues			
Device dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (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

Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (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
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 16 (43.75%)	2 / 3 (66.67%)	4 / 8 (50.00%)
number of deaths (all causes)	2	0	1
number of deaths resulting from adverse events			
Investigations			
GRAM POSITIVE COCCI			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme abnormal			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
White blood cell count increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Injury, poisoning and procedural complications			
Arterial injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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
Hip fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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
Joint dislocation			

subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	2 / 16 (12.50%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
General physical health deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Drug hypersensitivity			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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			
Constipation			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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

Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Haemoptysis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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
Lung infiltration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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

Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Mental status changes			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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			
Abdominal abscess			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Fungal infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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
Sepsis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (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
Product issues			
Device dislocation			

subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (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 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hypoglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (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
Hypophosphataemia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	PF-03084014 40 mg BID in Solid Tumor Subjects	PF-03084014 20 mg BID in Solid Tumor Subjects	PF-03084014 100 mg BID in Solid Tumor Subjects
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	7 / 8 (87.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Central nervous system leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Meningioma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Lymphoedema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Peripheral vascular disorder subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Vena cava thrombosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Chills			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	1 / 8 (12.50%)
occurrences (all)	3	2	2
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			

Contrast media allergy subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Reproductive system and breast disorders			
Amenorrhoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Breast disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Scrotal mass subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Sexual dysfunction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Cough subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Dysphonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	1 / 8 (12.50%) 1
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1

Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Throat irritation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Psychiatric disorders			
Affective disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Depressed mood subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Enuresis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hallucination subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Obsessive-compulsive disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Investigations			

Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	1 / 8 (12.50%) 4
Alpha 1 foetoprotein increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	1 / 8 (12.50%) 2
Bacterial test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	1 / 8 (12.50%) 1
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fungal test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Palpitations			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Intracranial aneurysm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Memory impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Neuralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Paraparesis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Presyncope subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Sinus headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Speech disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Leukopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Orbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Photophobia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Ascites			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	2 / 8 (25.00%)
occurrences (all)	0	3	2
Oesophageal ulcer haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	3	1	0
Ocular icterus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
PRURITIS			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Exfoliative rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nail bed disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Photosensitivity reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Rash subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	2 / 3 (66.67%) 3	1 / 8 (12.50%) 2
Rash erythematous subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Rash macular subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Rash pruritic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Skin lesion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Skin ulcer subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Renal pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bone cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bone swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint hyperextension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Osteopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lung infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Decreased appetite subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	2 / 3 (66.67%) 2	1 / 8 (12.50%) 1
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Fluid overload subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Fluid retention subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 2	0 / 8 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1

Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 8 (25.00%) 2
Malnutrition subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0

Non-serious adverse events	PF-03084014 80 mg BID in Solid Tumor Subjects	PF-03084014 130 mg BID in Solid Tumor Subjects	PF-03084014 150 mg BID in Solid Tumor Subjects
Total subjects affected by non-serious adverse events subjects affected / exposed	4 / 4 (100.00%)	3 / 4 (75.00%)	23 / 23 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Central nervous system leukaemia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Lipoma subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Meningioma subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 23 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 23 (4.35%) 2
Hot flush subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	1 / 23 (4.35%) 1

Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Peripheral vascular disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	1 / 4 (25.00%)	12 / 23 (52.17%)
occurrences (all)	4	1	14
General physical health deterioration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Induration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	1	0	2
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	3 / 23 (13.04%)
occurrences (all)	0	1	3
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Amenorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Breast disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Scrotal mass			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sexual dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	5 / 23 (21.74%)
occurrences (all)	1	3	5
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	4
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	5
Pleural effusion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Enuresis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	2	0	1
Alpha 1 foetoprotein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	2	0	1
Bacterial test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Fungal test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Meniscus injury			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Procedural pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Wound complication			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular disorder			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	3
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Hypoaesthesia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Intracranial aneurysm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Paraparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	2	0	3
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 23 (0.00%) 0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Orbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	4
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	3 / 23 (13.04%)
occurrences (all)	1	0	3
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	3 / 4 (75.00%)	15 / 23 (65.22%)
occurrences (all)	5	5	28
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	3
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Faeces soft			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	3 / 4 (75.00%)	14 / 23 (60.87%)
occurrences (all)	1	4	21
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	10 / 23 (43.48%)
occurrences (all)	1	2	13
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	3
Ocular icterus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
PRURITIS			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Blister			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	3
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Exfoliative rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	5
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Rash macular			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Skin ulcer			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	3	0	2
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Bone cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bone swelling			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Joint hyperextension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	3
Eye infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 23 (4.35%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 23 (0.00%)
occurrences (all)	0	1	0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	1 / 4 (25.00%)	2 / 4 (50.00%)	2 / 23 (8.70%)
occurrences (all)	1	2	2
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	3 / 23 (13.04%)
occurrences (all)	0	1	3
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 23 (8.70%)
occurrences (all)	0	0	5
Urinary tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	7 / 23 (30.43%)
occurrences (all)	0	1	9
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	3 / 23 (13.04%)
occurrences (all)	0	0	3
Diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Fluid overload			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Fluid retention			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	5 / 23 (21.74%)
occurrences (all)	1	1	5
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 23 (4.35%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	2 / 4 (50.00%)	2 / 4 (50.00%)	6 / 23 (26.09%)
occurrences (all)	3	2	18
Malnutrition			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 23 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	PF-03084014 220 mg BID in Solid Tumor Subjects	PF-03084014 330 mg BID in Solid Tumor Subjects	PF-03084014 in T-ALL/LBL Subjects
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	3 / 3 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Central nervous system leukaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Lipoma subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Meningioma subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Tumour haemorrhage subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Tumour pain subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 3	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Vascular disorders Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Lymphoedema subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Peripheral vascular disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Vena cava thrombosis subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Chest discomfort			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Early satiety			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	7 / 16 (43.75%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	11	2	0
General physical health deterioration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Induration			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 16 (0.00%)	2 / 3 (66.67%)	0 / 8 (0.00%)
occurrences (all)	0	3	0

Oedema peripheral subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	1 / 3 (33.33%) 1	2 / 8 (25.00%) 3
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Reproductive system and breast disorders Amenorrhoea subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Breast disorder subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Scrotal mass subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Sexual dysfunction subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Cough			

subjects affected / exposed	5 / 16 (31.25%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	5	2	2
Dysphonia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 16 (12.50%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	2 / 16 (12.50%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	2	0	1
Hypoxia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	8
Nasal congestion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Pleural effusion			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Pulmonary embolism			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Throat irritation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Confusional state			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Depressed mood			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Depression			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Enuresis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hallucination subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Insomnia subjects affected / exposed occurrences (all)	3 / 16 (18.75%) 3	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Obsessive-compulsive disorder subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	2 / 8 (25.00%) 5
Alpha 1 foetoprotein increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 16 (12.50%) 2	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Bacterial test positive subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	1 / 8 (12.50%) 3
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	2 / 8 (25.00%) 4
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood urea increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fungal test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	5
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	5
Haemoglobin decreased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Platelet count decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Prothrombin time prolonged			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	3	0	0
Transaminases increased			

subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
White blood cell count increased			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Fall			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Meniscus injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rib fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Stoma site pain			

subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Wound complication			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Sinus tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Cerebrovascular disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Dysgeusia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dyskinesia			

subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	3 / 16 (18.75%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	3	3	1
Hypoaesthesia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Intracranial aneurysm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Paraparesis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Presyncope			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Sinus headache			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Speech disorder			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	3
Leukocytosis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Leukopenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Neutropenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Splenomegaly			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye movement disorder			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye pain			

subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Orbital oedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Vitreous floaters			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 16 (12.50%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	2 / 16 (12.50%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	2	1	2
Diarrhoea			
subjects affected / exposed	12 / 16 (75.00%)	3 / 3 (100.00%)	2 / 8 (25.00%)
occurrences (all)	18	4	7
Dry mouth			
subjects affected / exposed	5 / 16 (31.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	5	1	0
Dyspepsia			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	2 / 8 (25.00%)
occurrences (all)	1	2	2
Dysphagia			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	8 / 16 (50.00%)	2 / 3 (66.67%)	5 / 8 (62.50%)
occurrences (all)	11	3	11
Oesophageal ulcer haemorrhage			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Toothache subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	5 / 16 (31.25%) 8	2 / 3 (66.67%) 4	5 / 8 (62.50%) 5
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Ocular icterus subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	1 / 8 (12.50%) 1
Skin and subcutaneous tissue disorders PRURITIS subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Blister subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Cold sweat subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Dermal cyst subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 2	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Dermatitis acneiform subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	0 / 3 (0.00%) 0	0 / 8 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1	1 / 3 (33.33%) 1	0 / 8 (0.00%) 0
Exfoliative rash			

subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail bed disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	3 / 16 (18.75%)	2 / 3 (66.67%)	0 / 8 (0.00%)
occurrences (all)	3	2	0
Rash erythematous			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Dysuria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Renal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 16 (12.50%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	2	4	0
Back pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Bone cyst			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Bone swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Joint hyperextension			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Joint stiffness			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Joint swelling			

subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Osteopenia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Infections and infestations			
Candida infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	3	0
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Viral infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	3 / 16 (18.75%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	4	2	0
Dehydration			
subjects affected / exposed	1 / 16 (6.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Diabetes mellitus			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Fluid overload			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fluid retention			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	3
Hypocalcaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			

subjects affected / exposed	2 / 16 (12.50%)	1 / 3 (33.33%)	1 / 8 (12.50%)
occurrences (all)	2	2	1
Hypomagnesaemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Hyponatraemia			
subjects affected / exposed	1 / 16 (6.25%)	0 / 3 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	9 / 16 (56.25%)	1 / 3 (33.33%)	0 / 8 (0.00%)
occurrences (all)	17	4	0
Malnutrition			
subjects affected / exposed	0 / 16 (0.00%)	0 / 3 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The study components related to combination therapy with dexamethasone were removed due to operational and scientific reasons.
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Notes: