Clinical trial results:
A Phase 2, Prospective, Randomized, Multicenter, Double-blind, Active-control, Parallel-group Study to Determine the Safety of and to Select a Treatment Regimen of CC-4047 (Pomalidomide) Either as Single-agent or in Combination With Prednisone to Study Further in Subjects With Myelofibrosis With Myeloid Metaplasia

Summary

EudraCT number	2006-004553-17
Trial protocol	GB ES AT IT DE
Global end of trial date	24 September 2013

Results information

Result version number	v1 (current)
This version publication date	14 July 2016
First version publication date	07 August 2015

Trial information

Trial identification

Sponsor protocol code	CC-4047-MMM-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00463385
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Celgene Corporation
Sponsor organisation address	86 Morris Avenue, Summit, NJ, United States, 07901
Public contact	Clinical Trial Disclosure 86 Morris Avenue Summit, NJ 07901, Celgene Corporation 86 Morris Avenue Summit, NJ 07901, 1 866-260-1599, ClinicalTrialDisclosure@Celgene.com
Scientific contact	Robert Gale, MD 86 Morris Avenue Summit, NJ 07901, Robert Gale, MD Celgene Corporation 86 Morris Avenue Summit, NJ 07901, RGale@Celgene.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	13 November 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 September 2013
Global end of trial reached?	Yes
Global end of trial date	24 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To select a treatment regimen of CC-4047 either as single-agent or in combination with prednisone to study further in subjects with myelofibrosis with myeloid metaplasia (MMM).

Protection of trial subjects:

Protection of Subjects by Institutional Review Board/Independent Ethics Committee Review and Approval; Protection of Patient Confidentiality

Background therapy: -

Evidence for comparator:

This study in MMM was designed to determine the appropriate CC-4047 dose and regimen as a monotherapy or in combination with prednisone. The comparator (prednisone monotherapy) facilitates the description of the Adverse Event (AE) profile of CC-4047. The prednisone control arm also allowed for a comparison in response rates of the CC-4047 mono- and combination therapies; thus providing a reasonable basis of information for designing further studies should the outcomes be in favor of a CC-4047 arm.

Actual start date of recruitment	19 April 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Austria: 5
Country: Number of subjects enrolled	Italy: 28
Country: Number of subjects enrolled	United States: 52
Worldwide total number of subjects	88
EEA total number of subjects	36

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)	35
From 65 to 84 years	52
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were entered into the Pre-randomization phase and were evaluated for the inclusion and exclusion criteria for the Double-Blind Treatment Phase of the study. The Pre-Randomization Phase did not last more than 28 days. However, the bone marrow histology for diagnosis may have preceded this period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Blinding implementation details:

A double-blind technique was used and was chosen to minimize bias on the part of participants, investigators, and the sponsor. Identical placebo capsules were supplied to match the 0.5 mg and 1.0 mg pomalidomide capsules. Placebo to match prednisone was also provided. The blind was not to be broken during the Double-Blind Treatment Phase unless in the opinion of the investigator it was absolutely needed to safely treat the subject. The medical monitor was to be contacted prior to unblinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Prednisone

Arm description:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study.

Arm type	Active comparator
Investigational medicinal product name	Prednisone
Investigational medicinal product code	H02 AB07
Other name	Deltasone; Orasone
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study.

Investigational medicinal product name	Pomalidomide Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study.

Arm title	Pomalidomide 2 mg

Arm description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Arm type	Experimental
Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	CC-4047
Other name	Imnovid; Pomalyst
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal

Investigational medicinal product name	Prednisone Placebo
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase.

After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Arm title	Pomalidomide 2 mg + Prednisone

Arm description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Arm type	Experimental
Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	CC-4047
Other name	Imnovid; Pomalyst
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.
Period Title: Overall Study

Investigational medicinal product name	Prednisone
Investigational medicinal product code	H02 AB07
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal

Arm title	Pomalidomide 0.5 mg + Prednisone

Arm description:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Arm type	Experimental
Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	CC-4047
Other name	Imnovid
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.
Period Title: Overall Study

Investigational medicinal product name	Predisone
Investigational medicinal product code	H02 AB07
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Number of subjects in period 1	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone
Started	22	22	22
Treated	22	22	19
Completed	0	0	0
Not completed	22	22	22
Consent withdrawn by subject	3	3	3
Adverse event, non-fatal	5	8	4
Death	2	1	2
Unspecified	4	3	6
Lost to follow-up	-	-	-
Missing	2	-	-
Disease Progression	6	6	7
1 participant received commercial drug	-	1	-

Number of subjects in period 1	Pomalidomide 0.5 mg + Prednisone
Started	22
Treated	22
Completed	0
Not completed	22
Consent withdrawn by subject	4
Adverse event, non-fatal	2
Death	-
Unspecified	4
Lost to follow-up	1
Missing	2
Disease Progression	9
1 participant received commercial drug	-

Baseline characteristics

Reporting groups

Reporting group title	Prednisone

Reporting group description:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study.

Reporting group title	Pomalidomide 2 mg

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group title	Pomalidomide 2 mg + Prednisone

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group title	Pomalidomide 0.5 mg + Prednisone

Reporting group description:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone
Number of subjects	22	22	22
Age categorical Units: Subjects			
Adults (18-64 years)	10	8	8
From 65-84 years	12	14	14
85 years and over	0	0	0
Age continuous Units: years			
median	66	68	67.5
full range (min-max)	44 to 80	50 to 83	36 to 82
Gender categorical Units: Subjects			
Female	8	5	7
Male	14	17	15

Race/Ethnicity Units: Subjects			
White	21	22	21
Black	0	0	1
Hispanic	1	0	0
Janus kinase 2 (JAK2) Mutation			
JAK2^V617F mutation result based on quantitative polymerase chain reaction (PCR) analysis in neutrophil preparation.			
Units: Subjects			
Negative	6	7	8
Positive	13	11	10
Missing	3	4	4
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status scale and criteria used to assess disease progression, how the disease affects the daily living abilities of the patient, and determine appropriate treatment: 0= Fully active, able to carry on all pre-disease activities; 1= Restricted in physically strenuous activity; ambulatory and able to carry out light work; 2= Ambulatory and capable of all selfcare; unable to perform work activities. Up and about > 50% of waking hours; 3= Capable of only limited selfcare, confined to bed/chair > 50% of waking hours; 4= Completely disabled. Confined to bed or chair; 5= Dead			
Units: Subjects			
Grade 0	12	11	6
Grade 1	8	9	10
Garde 2	2	2	5
Missing	0	0	1
Myelofibrosis with myeloid metaplasia Subtype Units: Subjects			
Agnogenic Myeloid Metaplasia (AMM)	16	16	16
Postpolycythemic Myeloid Metaplasia (PPMM)	3	4	4
Postthromocythemic Myeloid Metaplasia (PTMM)	3	2	2
Red Blood Cell (RBC) Transfusion Dependence [1]			
A patient who receives at least a total of two units of RBC transfusion within 28 days on or prior to the first study drug dosing date is an RBC-transfusion-dependent patient. Otherwise a patient is an RBC-transfusion-independent patient.			
Units: Subjects			
Yes	12	10	9
No	10	12	13
Time Since Myelofibrosis Diagnosis Units: Years			
median	1.5	0.6	1.1
full range (min-max)	0 to 14.3	0 to 6.3	0 to 13
RBC Transfusion Burden Units: units/28 days			
median	2	1	0
full range (min-max)	0 to 7	0 to 6	0 to 6

Reporting group values	Pomalidomide 0.5 mg + Prednisone	Total	
Number of subjects	22	88	

Age categorical Units: Subjects			
Adults (18-64 years)	9	35	
From 65-84 years	12	52	
85 years and over	1	1	
Age continuous Units: years			
median	69.5		
full range (min-max)	43 to 86	-	
Gender categorical Units: Subjects			
Female	9	29	
Male	13	59	
Race/Ethnicity Units: Subjects			
White	22	86	
Black	0	1	
Hispanic	0	1	
Janus kinase 2 (JAK2) Mutation			
JAK2^V617F mutation result based on quantitative polymerase chain reaction (PCR) analysis in neutrophil preparation.			
Units: Subjects			
Negative	8	29	
Positive	9	43	
Missing	5	16	
Eastern Cooperative Oncology Group (ECOG) Performance Status			
ECOG performance status scale and criteria used to assess disease progression, how the disease affects the daily living abilities of the patient, and determine appropriate treatment: 0= Fully active, able to carry on all pre-disease activities; 1= Restricted in physically strenuous activity; ambulatory and able to carry out light work; 2= Ambulatory and capable of all selfcare; unable to perform work activities. Up and about > 50% of waking hours; 3= Capable of only limited selfcare, confined to bed/chair > 50% of waking hours; 4= Completely disabled. Confined to bed or chair; 5= Dead			
Units: Subjects			
Grade 0	14	43	
Grade 1	6	33	
Garde 2	2	11	
Missing	0	1	
Myelofibrosis with myeloid metaplasia Subtype Units: Subjects			
Agnogenic Myeloid Metaplasia (AMM)	13	61	
Postpolycythemic Myeloid Metaplasia (PPMM)	2	13	
Postthromocythemic Myeloid Metaplasia (PTMM)	7	14	
Red Blood Cell (RBC) Transfusion Dependence [1]			
A patient who receives at least a total of two units of RBC transfusion within 28 days on or prior to the first study drug dosing date is an RBC-transfusion-dependent patient. Otherwise a patient is an RBC-transfusion-independent patient.			
Units: Subjects			

Yes	12	43	
No	10	45	

Time Since Myelofibrosis Diagnosis			
Units: Years			
median	1.7		
full range (min-max)	0 to 10.9	-	
RBC Transfusion Burden			
Units: units/28 days			
median	1		
full range (min-max)	0 to 7	-	

End points

End points reporting groups

Reporting group title	Prednisone

Reporting group description:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study.

Reporting group title	Pomalidomide 2 mg

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group title	Pomalidomide 2 mg + Prednisone

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group title	Pomalidomide 0.5 mg + Prednisone

Reporting group description:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Primary: Percentage of Participants With a Clinical Response Within the First 6 Cycles of Treatment

End point title	Percentage of Participants With a Clinical Response Within the First 6 Cycles of Treatment

End point description:

A clinical responder was defined as either:
a. A baseline red blood cell (RBC)-transfusion-dependent participant with a ≥ 56 consecutive day RBC transfusion-free period after the first dose of study drug, or
b. A baseline RBC-transfusion-independent participant with an increase in hemoglobin of 2.0 g/dL or more from baseline for ≥ 56 consecutive days in the absence of RBC transfusions, or
c. A participant with either a ≥ 50% reduction in palpable splenomegaly of a spleen that was ≥ 10 cm at baseline or a spleen that was palpable at > 5 cm and became not palpable.
Participants who discontinued the study early without achieving clinical response were counted as non-responders. Modified intent-to-treat (MITT), defined as the patients who had a confirmed diagnosis of Myelofibrosis with myeloid metaplasia (MMM), received at least one dose of study drug, and participated in the study for at least 56 days.

End point type	Primary

End point timeframe:

Up to 168 days

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	19	21
Units: percentage of participants				
number (confidence interval 95%)	55 (31.53 to 76.94)	23.5 (6.81 to 49.9)	21.1 (6.05 to 45.57)	47.6 (25.71 to 70.22)

Statistical analyses

Statistical analysis title	Clinical Response
Statistical analysis description:	
Statistical Analysis 1 for Percentage of Participants With a Clinical Response Within the First 6 Cycles of Treatment	
Comparison groups	Prednisone v Pomalidomide 2 mg
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.092
Method	Fisher exact

Statistical analysis title	Clinical Response
Statistical analysis description:	
Participants With a Clinical Response Within the First 6 Cycles of Treatment	
Comparison groups	Prednisone v Pomalidomide 2 mg + Prednisone
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.048
Method	Fisher exact

Statistical analysis title	Clinical Response
Statistical analysis description:	
Participants With a Clinical Response Within the First 6 Cycles of Treatment	
Comparison groups	Prednisone v Pomalidomide 0.5 mg + Prednisone

Number of subjects included in analysis	41
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.758
Method	Fisher exact

Secondary: Percentage of Participants With a Clinical Response Within the First 12 Cycles of Treatment

End point title	Percentage of Participants With a Clinical Response Within the First 12 Cycles of Treatment

End point description:

A clinical responder was defined as either:
a. A baseline red blood cell (RBC)-transfusion-dependent participant with a ≥ 56 consecutive day RBC transfusion-free period after the first dose of study drug, or
b. A baseline RBC-transfusion-independent participant with an increase in hemoglobin of 2.0 g/dL or more from baseline for ≥ 56 consecutive days in the absence of RBC transfusions, or
c. A participant with either a ≥ 50% reduction in palpable splenomegaly of a spleen that was ≥ 10 cm at baseline or a spleen that was palpable at > 5 cm and became not palpable.
Participants who discontinued the study early without achieving clinical response were counted as non-responders.
Intent-to-treat (ITT), defined as all patients who were randomized, independent of whether they received study treatment or not.

End point type	Secondary

End point timeframe:

Up to 336 days

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	22	22	22
Units: Percentage of participants				
number (confidence interval 95%)	50 (28.22 to 71.78)	18.2 (5.19 to 40.28)	18.2 (5.19 to 40.28)	45.5 (24.39 to 67.79)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to the First Clinical Response

End point title	Time to the First Clinical Response

End point description:

Title: Time to the First Clinical Response
Description: The time to the first clinical response achieved within 168 days after the first study drug dosing date was calculated for participants who achieved a clinical response as:
Start date of the first clinical response - the first study drug date +1.
A clinical responder was defined as either:
a. A baseline red blood cell (RBC)-transfusion-dependent participant with a ≥ 56 consecutive day RBC transfusion-free period after the first dose of study drug, or
b. A baseline RBC-transfusion-independent participant with an increase in hemoglobin of 2.0 g/dL or

more from baseline for ≥ 56 consecutive days in the absence of RBC transfusions, or
c. A participant with either a ≥ 50% reduction in palpable splenomegaly of a spleen that was ≥ 10 cm at baseline or a spleen that was palpable at > 5 cm and became not palpable.
Intent-to-treat population with a clinical response

End point type	Secondary

End point timeframe:

Up to 168 days

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4	4	10
Units: weeks				
median (full range (min-max))	0.3 (0.1 to 15.6)	8 (2.6 to 17.3)	10.1 (0.1 to 20)	1.2 (0.1 to 16.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of First Clinical Response

End point title	Duration of First Clinical Response

End point description:

For RBC-transfusion-dependent patients, duration of response was calculated as the last day of response - first day of response +1, where the last day of response was the date of the first RBC-transfusion administered at or more than 56 days after the response started. For patients who did not receive a subsequent transfusion after the response started, the end date of response was censored at the day of last hemoglobin assessment.
For RBC-transfusion-independent patients, the duration of response was calculated as the last day of response - first day of response +1, where the last day of response was the earlier of the date of a hemoglobin increase of < 2.0 g/dL and the date of a RBC transfusion at ≥ 56 days after the response started. For patients whose hemoglobin measurements were always ≥ 2.0 g/dL and never received a RBC transfusion after response started, the end date of the response was censored at the date of last hemoglobin measurement.
Kaplan-Meier methodology was used.

End point type	Secondary

End point timeframe:

Up to 40 months

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	4[1]	4	10
Units: months				
median (confidence interval 95%)	3.7 (3 to 6.6)	9999 (4.7 to 9999)	6 (2.3 to 9.8)	10.6 (2.8 to 16.1)

Notes:

[1] - Median not estimable as only 1 patient progressed in this group as defined by 9999

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Cancer Therapy-Anemia (FACT-An) Subscale and Total Scores

End point title	Change From Baseline in Functional Assessment of Cancer Therapy-Anemia (FACT-An) Subscale and Total Scores

End point description:

The FACT-An comprises the four subscales of the 27-item FACT-General Scale (FACT-G), Physical Well-being, Social/Family Well-being, Emotion Well-being, Functional Well-Being, and the Additional Concerns Anemia subscale. Questions are rated on a scale from 0 to 4, where higher scores indicate more impact on quality of life.

- Physical Well-being consists of 7 questions, the subscale score ranges from 0-28;
- Social/Family Well-being consists of 7 questions, the subscale score ranges from 0-28;
- Emotion Well-being consists of 6 questions, the subscale score ranges from 0-24;
- Functional Well-Being consists of 7 questions, the subscale score ranges from 0-28;
- Anemia subscale consists of 20 questions, the subscale score ranges from 0-80;
- Total FACT-An score ranges from 0-188.

Intent-to-treat patients with available data.

End point type	Secondary

End point timeframe:

Baseline and Cycle 6 (168 days).

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	7	3	12
Units: units on a scale				
arithmetic mean (standard deviation)				
Physical Well-Being subscale	0.6 (± 1.5)	0.4 (± 6.42)	5.3 (± 4.04)	2.3 (± 2.26)
Social/Family Well-Being subscale	1.9 (± 3.08)	-1.9 (± 2.59)	1.7 (± 3.79)	0.9 (± 6.84)
Emotional Well-Being subscale	1.3 (± 3.32)	0 (± 4.76)	-0.3 (± 2.7)	1.7 (± 3.47)
Functional Well-Being subscale	0.9 (± 4.14)	-2.1 (± 8.99)	2.7 (± 3.06)	2.5 (± 6.5)
Anemia subscale	1.2 (± 9.47)	2.3 (± 21.34)	19.3 (± 18.93)	5.8 (± 8.85)
total Fact-Anemia Score	2.3 (± 12.42)	1.6 (± 36.51)	27.3 (± 25.74)	11.4 (± 13.51)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hemoglobin Concentration for Responders

End point title	Change From Baseline in Hemoglobin Concentration for

	Responders

End point description:

Change from Baseline in hemoglobin for participants with a clinical response within the first 6 cycles of treatment. Intent-to-treat participants with a clinical response and available hemoglobin values at each time point.

End point type	Secondary

End point timeframe:

Baseline, Cycle 6 (168 days)

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	2	0[2]	8
Units: g/dL				
median (full range (min-max))	1.4 (-0.5 to 4.1)	2 (0.7 to 3.2)	(to)	-0.1 (-1.9 to 3.9)

Notes:

[2] - No participants with a hemoglobin response in this group

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Hemoglobin Concentration for Non-Responders

End point title	Change From Baseline in Hemoglobin Concentration for Non-Responders

End point description:

Change from Baseline in hemoglobin for participants without a clinical response within the first 6 cycles of treatment. Intent-to-treat participants with no clinical response and available hemoglobin values at each time point.

End point type	Secondary

End point timeframe:

Baseline, Cycle 6 (168 days)

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	5	6
Units: g/dL				
median (full range (min-max))	1.2 (-0.2 to 2.7)	0.1 (-0.8 to 1.3)	-0.8 (-2 to 1.9)	0.5 (-0.3 to 1)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Likert Abdominal Pain Scale

End point title	Change From Baseline in Likert Abdominal Pain Scale

End point description:

Participants rated abdominal discomfort or pain over the previous week on a scale from zero to ten, where zero is no discomfort or pain and ten is the worst pain imaginable. Intent-to-treat patients with available data.

End point type	Secondary

End point timeframe:

Baseline and Cycle 6 (168 days)

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	7	3	12
Units: units on a scale				
arithmetic mean (standard deviation)	0.3 (± 1.83)	-1 (± 3.11)	0.3 (± 1.15)	-0.1 (± 1.68)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Adverse Events (AEs)

End point title	Number of Participants With Adverse Events (AEs)

End point description:

A serious AE (SAE) was defined as any AE which resulted in death or was life-threatening, required or prolonged inpatient hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or constituted an important medical event (events that may have jeopardized the patient or required intervention to prevent one of the outcomes listed above).
The severity of AEs were graded according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE, Version 3.0) or according to the following scale:
Grade 1 = Mild; Grade 2 = Moderate; Grade 3 = Severe; Grade 4 = Life-threatening; Grade 5 = Death.
The Investigator determined the relationship between study drug and the occurrence of an AE as "Not Related" or "Related" (since the study was double-blinded, a patient receiving only prednisone could have an AE that was judged as related to pomalidomide, and vice-versa). Safety population (all treated patients).

End point type	Secondary

End point timeframe:

From date of the first dose of the study drug until discontinuation or the data cut-off date (up to approximately 45 months).

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22	22	19	22
Units: Participants				
number (not applicable)				
At least one AE	20	21	18	21
At least one AE related to pomalidomide	15	17	16	15
At least one AE related to prednisone	10	10	11	5
At least one Grade 3-4 AE	10	14	13	15
At least one Grade 3-4 AE related to pomalidomide	6	7	11	6
At least one Grade 3-4 AE related to prednisone	5	2	6	3
At least one SAE	6	10	11	8
At least one SAE related to pomalidomide	4	6	8	3
At least one SAE related to prednisone	4	3	5	3
AE leading to discontinuation of pomalidomide	7	11	5	6
AE leading to discontinuation of prednisone	5	7	2	1
AE leading to a dose reduction of pomalidomide	0	2	1	1
AE leading to a dose interruption of pomalidomide	5	9	9	7
AE leading to a dose interruption of prednisone	2	8	6	3

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinical Response by Baseline JAK2 Positive Assessment

End point title	Percentage of Participants With Clinical Response by Baseline JAK2 Positive Assessment

End point description:

Percentage of participants who achieved a clinical response, presented by participants with positive janus kinase 2 (JAK2) V617F mutation results at Baseline. Includes Intent-to-treat population with non-missing JAK2 Baseline assessment results. The number of participants analyzed indicates the number of participants with a positive JAK2 result for each treatment group respectively.

End point type	Secondary

End point timeframe:

Up to 336 days

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13[3]	11[4]	10[5]	9[6]
Units: Percentage of participants				
number (not applicable)	46.2	27.3	30	66.7

Notes:

[3] - Includes those who were positive for the janus kinase 2 (JAK2) V617F results.

[4] - Includes those who were positive for the janus kinase 2 (JAK2) V617F results.

[5] - Includes those who were positive for the janus kinase 2 (JAK2) V617F results.

[6] - Includes those who were positive for the janus kinase 2 (JAK2) V617F results.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Clinical Response by Baseline JAK2 Negative Assessment

End point title	Percentage of Participants With Clinical Response by Baseline JAK2 Negative Assessment

End point description:

Percentage of participants who achieved a clinical response, presented by participants with negative janus kinase 2 (JAK2) V617F mutation results at Baseline. Includes Intent-to-treat population with non-missing JAK2 Baseline assessment results. The number of participants analyzed indicates the number of participants with a negative JAK2 result for each treatment group respectively.

End point type	Secondary

End point timeframe:

Up to 336 days

End point values	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone	Pomalidomide 0.5 mg + Prednisone
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6[7]	7[8]	8[9]	8[10]
Units: Percentage of participants who achieved				
number (not applicable)	50	28.6	12.5	25

Notes:

[7] - Includes those who were negative for the janus kinase 2 (JAK2) V617F results.

[8] - Includes those who were negative for the janus kinase 2 (JAK2) V617F results.

[9] - Includes those who were negative for the janus kinase 2 (JAK2) V617F results.

[10] - Includes those who were negative for the janus kinase 2 (JAK2) V617F results.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first dose of the study drug through to 30 days after the last dose; up to the data cut-off date of 18 December 2013; up to 81 months

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Prednisone

Reporting group description:

Participants received oral prednisone from Day 1-28 of each 28-day cycle for up to 3 cycles (84 days), 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day, and pomalidomide placebo tablets on Days 1-28 for up to 12 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, participants were discontinued from the study

Reporting group title	Pomalidomide 2 mg

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and prednisone placebo tablets on Days 1-28 for the first 3 cycles in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.
Period Title: Overall Study

Reporting group title	Pomalidomide 2 mg + Prednisone

Reporting group description:

Participants received 2 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone capsules on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 2 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Reporting group title	Pomalidomide 0.5 mg + Prednisone

Reporting group description:

Participants received 0.5 mg oral pomalidomide daily from Day 1-28 of each 28-day cycle for up to 12 cycles (336 days), and oral prednisone tablets on Days 1-28 for the first 3 cycles, 1st cycle = 30 mg daily, 2nd cycle = 15 mg daily, 3rd cycle = 15 mg every other day in the Double-Blind Treatment Phase. After the completion of cycle 12 and upon unblinding, eligible participants continued to receive oral pomalidomide 0.5 mg daily, from Days 1-28 of each cycle. Participants could remain on study treatment in the Extension Phase until disease progression, unacceptable toxicity or voluntary withdrawal.

Serious adverse events	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 22 (27.27%)	10 / 22 (45.45%)	11 / 19 (57.89%)
number of deaths (all causes)	2	3	4
number of deaths resulting from adverse events	2	3	3
Vascular disorders			
Deep Vein Thrombosis			

subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lung infiltration			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Pleural effusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Pulmonary hypertension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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 Failure			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Psychiatric disorders			
Mental Status Changes			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
International Normalised Ratio Increased			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Injury, poisoning and procedural complications			
Thoracic vertebral fracture			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Craniocerebral injury			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorders			
Atrial Fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Atrial Flutter			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (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
Bradycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Acute			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Left ventricular dysfunction			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Myocardial Infarction			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (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
Right ventricular failure			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Cognitive disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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 encephalopathy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Memory Impairment			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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 and lymphatic system disorders			

Acquired Von Willebrand Disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Anaemia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic Anaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Leukocytosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Varices oesophageal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal Failure			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			

subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Chronic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Lung infection pseudomonal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Cellulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Diverticulitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Lobar Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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

Perirectal abscess			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 22 (4.55%)	3 / 22 (13.64%)	3 / 19 (15.79%)
occurrences causally related to treatment / all	1 / 1	1 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (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
Fluid retention			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (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
Hyperglycaemia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Pomalidomide 0.5 mg + Prednisone		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 22 (36.36%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chills			

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease Progression				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Cardiac Chest Pain				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Hypoxia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary Embolism				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				

subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory Failure				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental Status Changes				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
International Normalised Ratio Increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Thoracic vertebral fracture				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial Fibrillation				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial Flutter				

subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure Acute				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Left ventricular dysfunction				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial Infarction				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebral haemorrhage				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular Accident				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic encephalopathy				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Memory Impairment				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Acquired Von Willebrand Disease				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	2 / 22 (9.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Eosinophilia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile Neutropenia				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic Anaemia				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varices oesophageal			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal Failure			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure Acute			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure Chronic			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue			

disorders			
Lung infection pseudomonal			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lobar Pneumonia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences causally related to treatment / all	2 / 5		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Septic shock				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection enterococcal				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Cachexia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fluid retention				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperuricaemia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Prednisone	Pomalidomide 2 mg	Pomalidomide 2 mg + Prednisone
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 22 (90.91%)	20 / 22 (90.91%)	17 / 19 (89.47%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Hypotension			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 22 (4.55%)	3 / 22 (13.64%)	1 / 19 (5.26%)
occurrences (all)	1	4	1
Chills			
subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	4	2	2
Fatigue			
subjects affected / exposed	6 / 22 (27.27%)	2 / 22 (9.09%)	6 / 19 (31.58%)
occurrences (all)	17	3	12
Feeling jittery			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gait Disturbance			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	8	0
Oedema			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			

subjects affected / exposed	6 / 22 (27.27%)	8 / 22 (36.36%)	10 / 19 (52.63%)
occurrences (all)	7	8	24
Pain			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 22 (27.27%)	6 / 22 (27.27%)	4 / 19 (21.05%)
occurrences (all)	6	6	4
Dysphonia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	0	1	4
Dyspnoea			
subjects affected / exposed	7 / 22 (31.82%)	7 / 22 (31.82%)	3 / 19 (15.79%)
occurrences (all)	7	9	6
Dyspnoea Exertional			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Epistaxis			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	5 / 19 (26.32%)
occurrences (all)	1	2	6
Nasal Congestion			
subjects affected / exposed	3 / 22 (13.64%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pleural Effusion			

subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Pleuritic Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pulmonary Hypertension			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Depression			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	1	2	1
Insomnia			
subjects affected / exposed	4 / 22 (18.18%)	2 / 22 (9.09%)	2 / 19 (10.53%)
occurrences (all)	6	2	2
Mental Status Changes			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Personality Change			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Investigations			
Cardiac Murmur			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Heart Rate Increased			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Weight decreased			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	2 / 19 (10.53%)
occurrences (all)	0	2	2
Excoriation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Sinus Bradycardia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Balance Disorder			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Burning Sensation			
subjects affected / exposed	3 / 22 (13.64%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dizziness			

subjects affected / exposed	4 / 22 (18.18%)	2 / 22 (9.09%)	6 / 19 (31.58%)
occurrences (all)	4	2	11
Dysgeusia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	2	2	0
Hypoaesthesia			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	2	2	2
Memory Impairment			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	1	3	3
Migraine			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	4 / 22 (18.18%)	2 / 22 (9.09%)	3 / 19 (15.79%)
occurrences (all)	5	2	4
Tremor			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 22 (9.09%)	5 / 22 (22.73%)	3 / 19 (15.79%)
occurrences (all)	2	7	4
Leukopenia			
subjects affected / exposed	0 / 22 (0.00%)	3 / 22 (13.64%)	0 / 19 (0.00%)
occurrences (all)	0	4	0
Neutropenia			
subjects affected / exposed	1 / 22 (4.55%)	5 / 22 (22.73%)	3 / 19 (15.79%)
occurrences (all)	1	21	13
Thrombocytopenia			
subjects affected / exposed	2 / 22 (9.09%)	5 / 22 (22.73%)	3 / 19 (15.79%)
occurrences (all)	2	10	9

Thrombocytosis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Eye disorders			
Eye Irritation			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Lacrimation Increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Periorbital Oedema			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	3 / 22 (13.64%)	2 / 22 (9.09%)	4 / 19 (21.05%)
occurrences (all)	3	6	4
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	4 / 22 (18.18%)	3 / 22 (13.64%)	1 / 19 (5.26%)
occurrences (all)	5	4	2
Abdominal Pain Upper			
subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	2	2	1
Ascites			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	4
Constipation			

subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	5 / 19 (26.32%)
occurrences (all)	2	6	6
Diarrhoea			
subjects affected / exposed	6 / 22 (27.27%)	6 / 22 (27.27%)	8 / 19 (42.11%)
occurrences (all)	7	10	13
Dyspepsia			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	5 / 19 (26.32%)
occurrences (all)	0	2	5
Flatulence			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Gingival bleeding			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Nausea			
subjects affected / exposed	4 / 22 (18.18%)	4 / 22 (18.18%)	3 / 19 (15.79%)
occurrences (all)	5	5	7
Oral pain			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Tongue ulceration			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 22 (9.09%)	3 / 22 (13.64%)	1 / 19 (5.26%)
occurrences (all)	2	3	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	3

Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Ecchymosis			
subjects affected / exposed	1 / 22 (4.55%)	3 / 22 (13.64%)	1 / 19 (5.26%)
occurrences (all)	1	3	1
Erythema			
subjects affected / exposed	0 / 22 (0.00%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Increased Tendency To Bruise			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Night Sweats			
subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	3	2	1
Pruritus			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	1	2	2
Rash			
subjects affected / exposed	1 / 22 (4.55%)	8 / 22 (36.36%)	3 / 19 (15.79%)
occurrences (all)	1	14	3
Rash Pruritic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin Odour Abnormal			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Pollakiuria			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Urinary Incontinence			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 22 (0.00%)	3 / 22 (13.64%)	0 / 19 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 22 (13.64%)	3 / 22 (13.64%)	1 / 19 (5.26%)
occurrences (all)	5	3	1
Back Pain			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	2 / 19 (10.53%)
occurrences (all)	1	3	2
Bone Pain			
subjects affected / exposed	1 / 22 (4.55%)	3 / 22 (13.64%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
Muscle Spasms			
subjects affected / exposed	3 / 22 (13.64%)	1 / 22 (4.55%)	6 / 19 (31.58%)
occurrences (all)	4	1	6
Muscular Weakness			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	7	7	1
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pain In Extremity			
subjects affected / exposed	2 / 22 (9.09%)	4 / 22 (18.18%)	2 / 19 (10.53%)
occurrences (all)	2	5	3
Infections and infestations			

Cystitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Enterococcal Sepsis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	2 / 19 (10.53%)
occurrences (all)	2	3	2
Nasopharyngitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	2 / 22 (9.09%)	2 / 22 (9.09%)	0 / 19 (0.00%)
occurrences (all)	2	5	0
Respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	3 / 22 (13.64%)	2 / 22 (9.09%)	1 / 19 (5.26%)
occurrences (all)	3	3	1
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Gout			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Hyperglycaemia			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Non-serious adverse events	Pomalidomide 0.5 mg + Prednisone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 22 (95.45%)		
Vascular disorders			
Haematoma			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	7		
Chills			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	5		
Fatigue			
subjects affected / exposed	7 / 22 (31.82%)		
occurrences (all)	27		
Feeling jittery			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gait Disturbance			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	10 / 22 (45.45%)		
occurrences (all)	20		
Pain			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Immune system disorders			
Seasonal Allergy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 22 (36.36%)		
occurrences (all)	12		
Dysphonia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Dyspnoea			
subjects affected / exposed	6 / 22 (27.27%)		
occurrences (all)	24		
Dyspnoea Exertional			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	5		
Nasal Congestion			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	4		
Pleural Effusion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pleuritic Pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pulmonary Hypertension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Confusional State			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	5		
Mental Status Changes			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Personality Change			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Investigations			
Cardiac Murmur			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Heart Rate Increased			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Excoriation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Sinus Bradycardia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Balance Disorder			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Burning Sensation			

subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Dementia Alzheimer's type			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	8 / 22 (36.36%)		
occurrences (all)	37		
Dysgeusia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	5		
Hypoaesthesia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	12		
Memory Impairment			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	15		
Tremor			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	12		
Leukopenia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	5		

Neutropenia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	6		
Thrombocytopenia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Thrombocytosis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Ear congestion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye Irritation			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	10		
Lacrimation Increased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Periorbital Oedema			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	10		
Vision blurred			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Abdominal Pain			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	12		
Abdominal Pain Upper			

subjects affected / exposed	3 / 22 (13.64%)			
occurrences (all)	3			
Ascites				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	4 / 22 (18.18%)			
occurrences (all)	19			
Diarrhoea				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences (all)	6			
Dyspepsia				
subjects affected / exposed	3 / 22 (13.64%)			
occurrences (all)	6			
Flatulence				
subjects affected / exposed	2 / 22 (9.09%)			
occurrences (all)	2			
Gastrooesophageal Reflux Disease				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences (all)	0			
Gingival bleeding				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences (all)	1			
Oral pain				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences (all)	1			
Tongue ulceration				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences (all)	0			
Vomiting				

subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	8		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dry Skin			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	5		
Increased Tendency To Bruise			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Night Sweats			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	8		
Pruritus			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	6		
Rash			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	6		
Rash Pruritic			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin Odour Abnormal			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Urinary Incontinence			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	5		
Back Pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Bone Pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Muscle Spasms			
subjects affected / exposed	5 / 22 (22.73%)		
occurrences (all)	6		
Muscular Weakness			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	4		
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	24		
Osteoarthritis			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pain In Extremity			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Enterococcal Sepsis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Nasopharyngitis			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	7		
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Urinary tract infection			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	4		
Gout			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Hyperuricaemia			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Hypokalaemia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 January 2008	For the European Union only and the following included: 1. The inclusion of new study personnel and central lab 2. The pomalidomide warning label and handling instructions 4. Allowing for additional visits, and minor administrative wording changes
13 August 2008	The protocol was amended (for all countries) to add the extension phase and for miscellaneous minor changes
13 February 2009	The protocol was amended (for all countries) to update information on: 1. An update to the study drug packaging and storage 2. A revision to the extension phase from 12 cycles to open-ended for responders 3. Minor grammatical revisions.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported