



Clinical trial results:

A Randomized Phase 3 Study of AM0010 in Combination with FOLFOX Compared with FOLFOX Alone as Second-line Therapy in Patients with Metastatic Pancreatic Cancer that has Progressed During or Following a First-Line Gemcitabine Containing Regimen

Summary

EudraCT number	2016-003858-33
Trial protocol	AT ES DE BE GB PL FR IT
Global end of trial date	05 March 2020

Results information

Result version number	v1 (current)
This version publication date	30 August 2020
First version publication date	30 August 2020

Trial information

Trial identification

Sponsor protocol code	J1L-AM-JZGB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02923921
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 17158

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	05 March 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	05 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of pegilodecakin in combination with FOLFOX versus FOLFOX alone in participants with metastatic pancreatic cancer as measured by overall survival.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2017
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	36 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 182
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	Spain: 73
Country: Number of subjects enrolled	Canada: 9
Country: Number of subjects enrolled	Korea, Republic of: 89
Country: Number of subjects enrolled	Austria: 13
Country: Number of subjects enrolled	Belgium: 36
Country: Number of subjects enrolled	Taiwan: 15
Country: Number of subjects enrolled	Poland: 13
Country: Number of subjects enrolled	Italy: 67
Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Australia: 30
Country: Number of subjects enrolled	Germany: 20
Worldwide total number of subjects	567
EEA total number of subjects	242

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)	278
From 65 to 84 years	286
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

In the Participant Flow, participants who completed were those who died due to any cause or were alive and on study at conclusion but off treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Pegilodecakin + FOLFOX

Arm description:

Pegilodecakin 5 microgram per kilogram ($\mu\text{g/kg}$) dosed as one of the following 2 fixed doses: 0.4 milligram (mg) for participants weighing less than or equal to (\leq) 80 kg or 0.8 mg for participants weighing greater than ($>$) 80 kg on Days 1-5 and Days 8-12 subcutaneously (SC) plus FOLFOX [dl-Leucovorin (dl-LV) 400 milligram per meter square (mg/m^2) and oxaliplatin 85 mg/m^2 followed by bolus 5-fluorouracil (5-FU) 400 mg/m^2 and a 46 to 48 hour infusion of 5-FU 2400 mg/m^2] initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression. After discontinuation of FOLFOX in the absence of tumor progression [that is (i.e., completion of the planned 12 cycles or unacceptable FOLFOX related toxicity), Pegilodecakin 10 $\mu\text{g/kg}$ maintenance treatment administered as one of the 2 fixed doses, either 0.8 mg for participants weighing \leq 80 kg or 1.6 mg for participants weighing $>$ 80 kg.

Arm type	Experimental
Investigational medicinal product name	Pegilodecakin
Investigational medicinal product code	
Other name	LY3500518,AM0010
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Pegilodecakin 5 $\mu\text{g/kg}$ dosed as one of the following 2 fixed doses: 0.4 mg for participants weighing \leq 80 kg or 0.8 mg for participants weighing $>$ 80 kg on Days 1-5 and Days 8-12 subcutaneously (SC) on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression. . After discontinuation of FOLFOX in the absence of tumor progression [that is (i.e., completion of the planned 12 cycles or unacceptable FOLFOX related toxicity), Pegilodecakin 10 $\mu\text{g/kg}$ maintenance treatment administered as one of the 2 fixed doses, either 0.8 mg for participants weighing \leq 80 kg or 1.6 mg for participants weighing $>$ 80 kg.

Investigational medicinal product name	FOLFOX: Oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Oxaliplatin 85 mg/m^2 given as IV infusion.

Investigational medicinal product name	FOLFOX: dl-Leucovorin/l-Leucovorinc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

dl-Leucovorin (dl-LV) 400 mg/m2 given as IV infusion on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Investigational medicinal product name	FOLFOX: 5-fluorouracil (5-FU)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

5-fluorouracil (5-FU) 400 mg/m2 bolus and a 5- FU 2400 mg/m2 continuous infusion over 46 to 48 hours given on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Arm title	FOLFOX
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Arm description:

FOLFOX (dl-LV 400 mg/m2 and oxaliplatin 85 mg/m2 followed by bolus 5- FU 400 mg/m2 and a 46-hour infusion of 5-FU 2400 mg/m2) initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Arm type	Active comparator
Investigational medicinal product name	FOLFOX: dl-Leucovorin/l-Leucovorinc
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

dl-Leucovorin (dl-LV) 400 mg/m2 given as IV infusion on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Investigational medicinal product name	FOLFOX: Oxaliplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Oxaliplatin 85 mg/m2 given as IV infusion.

Investigational medicinal product name	FOLFOX: 5-fluorouracil (5-FU)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

5-fluorouracil (5-FU) 400 mg/m2 bolus and a 5- FU 2400 mg/m2 continuous infusion over 46 to 48 hours given on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Number of subjects in period 1	Pegilodecakin + FOLFOX	FOLFOX
Started	283	284
Received at Least 1 Dose of Study Drug	278	251
Safety population	278	251
Completed	230	227
Not completed	53	57
Consent withdrawn by subject	6	13

Sponsor Decision	39	38
Lost to follow-up	1	-
Unknown, Not Collected	7	6

Baseline characteristics

Reporting groups

Reporting group title	Pegilodecakin + FOLFOX
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Reporting group description:

Pegilodecakin 5 microgram per kilogram ($\mu\text{g/kg}$) dosed as one of the following 2 fixed doses: 0.4 milligram (mg) for participants weighing less than or equal to (\leq) 80 kg or 0.8 mg for participants weighing greater than ($>$) 80 kg on Days 1-5 and Days 8-12 subcutaneously (SC) plus FOLFOX [dl-Leucovorin (dl-LV) 400 milligram per meter square (mg/m^2) and oxaliplatin 85 mg/m^2 followed by bolus 5-fluorouracil (5-FU) 400 mg/m^2 and a 46 to 48 hour infusion of 5- FU 2400 mg/m^2] initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression. After discontinuation of FOLFOX in the absence of tumor progression [that is (i.e., completion of the planned 12 cycles or unacceptable FOLFOX related toxicity), Pegilodecakin 10 $\mu\text{g/kg}$ maintenance treatment administered as one of the 2 fixed doses, either 0.8 mg for participants weighing \leq 80 kg or 1.6 mg for participants weighing $>$ 80 kg.

Reporting group title	FOLFOX
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Reporting group description:

FOLFOX (dl-LV 400 mg/m^2 and oxaliplatin 85 mg/m^2 followed by bolus 5- FU 400 mg/m^2 and a 46-hour infusion of 5-FU 2400 mg/m^2) initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Reporting group values	Pegilodecakin + FOLFOX	FOLFOX	Total
Number of subjects	283	284	567
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	63.8	64.1	
standard deviation	± 9.0	± 9.9	-
Gender categorical			
Units: Subjects			
Female	135	132	267
Male	148	152	300
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	9	6	15
Not Hispanic or Latino	263	265	528
Unknown or Not Reported	11	13	24
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1	0	1

Asian	59	55	114
Native Hawaiian or Other Pacific Islander	0	1	1
Black or African American	8	8	16
White	207	213	420
More than one race	0	0	0
Unknown or Not Reported	8	7	15
Region of Enrollment			
Units: Subjects			
United States	93	89	182
United Kingdom	5	4	9
Spain	42	31	73
Canada	2	7	9
South Korea	48	41	89
Austria	3	10	13
Belgium	17	19	36
Taiwan	5	10	15
Poland	8	5	13
Italy	28	39	67
France	9	2	11
Australia	14	16	30
Germany	9	11	20

End points

End points reporting groups

Reporting group title	Pegilodecakin + FOLFOX
Reporting group description: Pegilodecakin 5 microgram per kilogram ($\mu\text{g/kg}$) dosed as one of the following 2 fixed doses: 0.4 milligram (mg) for participants weighing less than or equal to (\leq) 80 kg or 0.8 mg for participants weighing greater than ($>$) 80 kg on Days 1-5 and Days 8-12 subcutaneously (SC) plus FOLFOX [dl-Leucovorin (dl-LV) 400 milligram per meter square (mg/m^2) and oxaliplatin 85 mg/m^2 followed by bolus 5-fluorouracil (5-FU) 400 mg/m^2 and a 46 to 48 hour infusion of 5-FU 2400 mg/m^2] initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression. After discontinuation of FOLFOX in the absence of tumor progression [that is (i.e., completion of the planned 12 cycles or unacceptable FOLFOX related toxicity), Pegilodecakin 10 $\mu\text{g/kg}$ maintenance treatment administered as one of the 2 fixed doses, either 0.8 mg for participants weighing ≤ 80 kg or 1.6 mg for participants weighing > 80 kg.	
Reporting group title	FOLFOX
Reporting group description: FOLFOX (dl-LV 400 mg/m^2 and oxaliplatin 85 mg/m^2 followed by bolus 5-FU 400 mg/m^2 and a 46-hour infusion of 5-FU 2400 mg/m^2) initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.	

Primary: Overall Survival

End point title	Overall Survival
End point description: Overall survival is defined as the time from date of randomization to the date of death (due to any cause). For participants whose last known status is alive at the data cutoff date for the analysis, time will be censored as the last contact date prior to the data cutoff date. Analysis population included all randomized participants. The number of participants censored were Pegilodecakin + FOLFOX = 63 and FOLFOX = 73.	
End point type	Primary
End point timeframe: Randomization to date of death from any cause (Up to 36 Months)	

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	284		
Units: Months				
median (confidence interval 95%)	5.78 (5.45 to 6.64)	6.28 (5.62 to 7.39)		

Statistical analyses

Statistical analysis title	Overall Survival
Statistical analysis description: The primary test to compare overall survival between treatment arms was the two-sided log-rank test, stratified by region and prior therapy. The estimate of the hazard ration (HR) - (Pegilodecakin + FOLFOX Arm / FOLFOX Arm) and the corresponding 95% CI was computed using a Cox proportional hazards model stratified by randomization stratification factors. Randomization stratification factors were based	

on the data recorded in interactive voice response system (IVRS).

Comparison groups	Pegilodecakin + FOLFOX v FOLFOX
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	= 0.6565
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.045
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.863
upper limit	1.265

Notes:

[1] - The primary test to compare overall survival between treatment arms was the two-sided log-rank test, stratified by region and prior therapy. The estimate of the hazard ratio (HR) - (Pegilodecakin + FOLFOX Arm / FOLFOX Arm) and the corresponding 95% CI was computed using a Cox proportional hazards model stratified by randomization stratification factors. Randomization stratification factors were based on the data recorded in interactive voice response system (IVRS).

Secondary: Progression Free Survival

End point title	Progression Free Survival
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End point description:

Progression free survival (PFS) is defined as the time from randomization to the date of the first documented tumor progression as determined by the investigator (per RECIST v1.1 criteria) or death due to any cause - whichever occurs first. For participants who received subsequent systemic anticancer therapy (after discontinuation from the study drug) prior to objectively determined PD or death, PFS was censored at the date of the last objective progression-free disease assessment prior to start of postdiscontinuation chemotherapy. If a participant did not have a complete baseline disease assessment, then PFS was censored at the enrollment date, regardless whether or not objectively determined PD or death had been observed for the participant. Analysis population included all randomized participants. The number of participants censored were Pegilodecakin + FOLFOX = 45 and FOLFOX = 86.

End point type	Secondary
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End point timeframe:

Randomization to Progressive Disease (PD) or Date of Death (Up to 36 Months)

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	284		
Units: Months				
median (confidence interval 95%)	2.14 (1.94 to 3.38)	2.10 (1.94 to 3.25)		

Statistical analyses

Statistical analysis title	Progression Free Survival
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Statistical analysis description:

The estimate of hazard ratio (HR) was stratified by region and prior therapy.

Comparison groups	Pegilodecakin + FOLFOX v FOLFOX
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8144
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.981
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.808
upper limit	1.19

Secondary: Percentage of Participants Achieving Complete Response (CR) or Partial Response (PR) [Objective Response Rate (ORR)] That Assessed by Investigator

End point title	Percentage of Participants Achieving Complete Response (CR) or Partial Response (PR) [Objective Response Rate (ORR)] That Assessed by Investigator
End point description:	Participants with confirmed complete response (CR), confirmed partial response (PR), stable disease (SD), or progressive disease (PD) according to Response Evaluation Criteria In Solid Tumors (RECIST, version 1.0) criteria, as well as participants with a not evaluable/tumor response unknown. CR: disappearance of all tumor lesions by investigator. Participants who discontinued study treatment (for reasons other than progression) before entering concurrent phase were considered to have non-evaluable response. Analysis population included all randomized participants.
End point type	Secondary
End point timeframe:	
Randomization to PD (Up to 36 Months)	

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	284		
Units: percentage of participants				
number (not applicable)	4.6	5.6		

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving Complete Res
Comparison groups	Pegilodecakin + FOLFOX v FOLFOX

Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7044 ^[2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	1.7

Notes:

[2] - P-value is calculated by Exact Cochran-Mantel-Haenszel test stratified by the randomization strata Prior Therapy - interactive voice response system (IVRS), Geographic Region - IVRS.

Secondary: Percentage of Participants With a Best Overall Response of Complete Response (CR), Partial Response (PR) or Stable Disease (SD): Disease Control Rate (DCR)

End point title	Percentage of Participants With a Best Overall Response of Complete Response (CR), Partial Response (PR) or Stable Disease (SD): Disease Control Rate (DCR)
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End point description:

Disease control rate (DCR) is the percentage of participants with a best overall response of CR, PR or SD as defined by RECIST v1.1 and assessed by investigators. Analysis population included all randomized participants.

End point type	Secondary
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End point timeframe:

Randomization to Objective Progressive Disease or Start of New Anti-Cancer Therapy (Up To 36 Months)

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	284		
Units: Percentage of participants				
number (not applicable)	42.8	36.6		

Statistical analyses

Statistical analysis title	Percentage of Participants With a Best Overall Re
Comparison groups	Pegilodecakin + FOLFOX v FOLFOX
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1463 ^[3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.8

Notes:

[3] - P-value is calculated by Exact Cochran-Mantel-Haenszel test stratified by the randomization strata Prior Therapy - interactive voice response system (IVRS), Geographic Region - IVRS.

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)
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End point description:

Duration of response was defined using RECIST v. 1.1 criteria as the time from the date criteria were met for the first objectively recorded CR or PR until the first date criteria for PD were met or death from any cause. Participants who were not known to have died and who did not have PD were censored at the date of the last tumor assessment prior to the date of any subsequent systemic anticancer therapy. Analysis population included all randomized participants who achieved an objective response of CR or PR. The number of participants censored were Pegilodecakin + FOLFOX = 4 and FOLFOX = 7.

End point type	Secondary
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End point timeframe:

Randomization to Progressive Disease (PD) or Date of Death (Up to 36 Months)

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	16		
Units: Months				
median (confidence interval 95%)	4.99 (3.45 to 7.06)	5.17 (3.75 to 5.72)		

Statistical analyses

Statistical analysis title	Duration of Objective Response (DOR)
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Statistical analysis description:

The estimate of hazard ratio (HR) was stratified by region and prior therapy.

Comparison groups	Pegilodecakin + FOLFOX v FOLFOX
Number of subjects included in analysis	29
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9952
Method	Log Rank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.008
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	2.741

Secondary: 12-Month Survival Rate

End point title	12-Month Survival Rate
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End point description:

The 12-month survival rate is defined as the percentage of participants who have not died 12 months after the date of randomization. Analysis population included all randomized participants.

End point type	Secondary
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End point timeframe:

From randomization to until the date of first documented date of death from any cause within 12 months, assessed up to 15 months

End point values	Pegilodecakin + FOLFOX	FOLFOX		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	284		
Units: Percentage of participants				
number (confidence interval 95%)	0.5 (0.1 to 2.7)	2.1 (0.4 to 6.5)		

Statistical analyses

Statistical analysis title	12-Month Survival Rate
Comparison groups	Pegilodecakin + FOLFOX v FOLFOX
Number of subjects included in analysis	567
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2999
Method	Log Rank
Parameter estimate	Mean difference (final values)
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.6
upper limit	1.4

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up To 18 Months

Adverse event reporting additional description:

All randomized participants who received at least one dose of study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Pegilodecakin + FOLFOX
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Reporting group description:

Pegilodecakin 5 microgram per kilogram (µg/kg) dosed as one of the following 2 fixed doses: 0.4 milligram (mg) for participants weighing ≤80 kg or 0.8 mg for participants weighing >80 kg on Days 1-5 and Days 8-12 subcutaneously (SC) plus FOLFOX [dl-Leucovorin (dl-LV) 400 milligram per meter square (mg/m²) and oxaliplatin 85 mg/m² followed by bolus 5-fluorouracil (5-FU) 400 mg/m² and a 46 to 48 hour infusion of 5-FU 2400 mg/m²] initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression. After discontinuation of FOLFOX in the absence of tumor progression [that is (i.e., completion of the planned 12 cycles or unacceptable FOLFOX related toxicity], Pegilodecakin 10µg/kg maintenance treatment administered as one of the 2 fixed doses, either 0.8 mg for participants weighing ≤80 kg or 1.6 mg for participants weighing >80 kg.

Reporting group title	FOLFOX
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Reporting group description:

FOLFOX (dl-LV 400 mg/m² and oxaliplatin 85 mg/m² followed by bolus 5-FU 400 mg/m² and a 46-hour infusion of 5-FU 2400 mg/m²) initiated on Day 1 of a 14-day cycles for up to 12 cycles or until disease progression.

Serious adverse events	Pegilodecakin + FOLFOX	FOLFOX	
Total subjects affected by serious adverse events			
subjects affected / exposed	123 / 278 (44.24%)	95 / 251 (37.85%)	
number of deaths (all causes)	14	7	
number of deaths resulting from adverse events	2	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
acute myeloid leukaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tumour pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
aortic embolus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
deep vein thrombosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
internal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
peripheral coldness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
euthanasia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
fatigue			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	1 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
general physical health deterioration			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	2 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
generalised oedema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperpyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
malaise			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

mucosal inflammation alternative dictionary used: MedDRA 23.0 subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple organ dysfunction syndrome alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
oedema peripheral alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyrexia alternative dictionary used: MedDRA 23.0 subjects affected / exposed	13 / 278 (4.68%)	7 / 251 (2.79%)	
occurrences causally related to treatment / all	6 / 15	2 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders anaphylactic reaction alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders prostatic obstruction alternative dictionary used: MedDRA 23.0 subjects affected / exposed ^[1]	1 / 144 (0.69%)	0 / 134 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

acute respiratory distress syndrome			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
asthma			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pleural effusion			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
pneumonitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
pulmonary embolism			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory acidosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
completed suicide			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
mental status changes			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
device breakage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
device failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
device occlusion			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	3 / 278 (1.08%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
blood bilirubin increased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	4 / 251 (1.59%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
craniocerebral injury			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibula fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip fracture			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
infusion related reaction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
overdose			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
angina pectoris			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 278 (0.00%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac arrest			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
cardiac failure acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
cerebral ischaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
cerebrovascular accident			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ischaemic stroke			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lethargy			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
metabolic encephalopathy			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
neuropathy peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
sciatica			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischaemic attack			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	2 / 5	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
febrile neutropenia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	3 / 278 (1.08%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	1 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
neutropenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	2 / 3	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
thrombocytopenia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	11 / 278 (3.96%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 14	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain lower			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ascites			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
colitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
constipation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	5 / 251 (1.99%)	
occurrences causally related to treatment / all	0 / 3	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
duodenal stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastric haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastritis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroduodenal ulcer			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastrointestinal stenosis			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
haematemesis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
ileal perforation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
large intestinal obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	2 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
obstruction gastric			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

oesophageal stenosis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
pancreatitis acute				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
small intestinal haemorrhage				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
small intestinal obstruction				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	3 / 278 (1.08%)	2 / 251 (0.80%)		
occurrences causally related to treatment / all	0 / 3	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
stomatitis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)		
occurrences causally related to treatment / all	1 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
upper gastrointestinal haemorrhage				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	1 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
vomiting				
alternative dictionary used: MedDRA 23.0				

subjects affected / exposed	7 / 278 (2.52%)	5 / 251 (1.99%)	
occurrences causally related to treatment / all	2 / 8	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
bile duct obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bile duct stenosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	6 / 278 (2.16%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 8	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
cholangitis acute			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholecystitis acute			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic cirrhosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic function abnormal			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hepatic pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaundice cholestatic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skin and subcutaneous tissue disorders			
rash maculo-papular			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
cystitis haemorrhagic			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
nephrolithiasis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
oliguria			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
renal failure			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract obstruction			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	0 / 278 (0.00%)	3 / 251 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
bursitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
flank pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
muscular weakness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
musculoskeletal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal sepsis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
bacteraemia			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	3 / 278 (1.08%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
bacterial disease carrier			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary sepsis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	2 / 251 (0.80%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
biliary tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	3 / 278 (1.08%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cholangitis infective			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile colitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	2 / 278 (0.72%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

device related infection				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	4 / 278 (1.44%)	0 / 251 (0.00%)		
occurrences causally related to treatment / all	1 / 5	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
device related sepsis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
diverticulitis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
enterobacter sepsis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
enterocolitis infectious				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
escherichia sepsis				
alternative dictionary used: MedDRA 23.0				
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
gastroenteritis				
alternative dictionary used: MedDRA 23.0				

subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
gastroenteritis norovirus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
klebsiella sepsis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
liver abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lower respiratory tract infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonsillar abscess			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumococcal sepsis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

pneumocystis jirovecii pneumonia alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pneumonia alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	7 / 278 (2.52%)	4 / 251 (1.59%)	
occurrences causally related to treatment / all	1 / 8	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
pneumonia cryptococcal alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
respiratory tract infection alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
sepsis alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	10 / 278 (3.60%)	4 / 251 (1.59%)	
occurrences causally related to treatment / all	2 / 10	0 / 4	
deaths causally related to treatment / all	2 / 2	0 / 1	
septic shock alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	4 / 278 (1.44%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
urinary tract infection alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
urosepsis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
viral infection			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
adult failure to thrive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
cachexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
decreased appetite			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
dehydration			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	3 / 278 (1.08%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetes mellitus			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic ketoacidosis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
diabetic metabolic decompensation			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	0 / 278 (0.00%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
failure to thrive			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hypercalcaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyperglycaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

hypokalaemia alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 278 (0.36%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hyponatraemia alternative dictionary used: MedDRA 23.0 subjects affected / exposed	2 / 278 (0.72%)	1 / 251 (0.40%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
lactic acidosis alternative dictionary used: MedDRA 23.0 subjects affected / exposed	1 / 278 (0.36%)	0 / 251 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Non-serious adverse events	Pegilodecakin + FOLFOX	FOLFOX	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	271 / 278 (97.48%)	240 / 251 (95.62%)	
Investigations			
aspartate aminotransferase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed	12 / 278 (4.32%)	14 / 251 (5.58%)	
occurrences (all)	17	22	
blood alkaline phosphatase increased alternative dictionary used: MedDRA 23.0 subjects affected / exposed	21 / 278 (7.55%)	15 / 251 (5.98%)	
occurrences (all)	28	20	
blood bilirubin increased alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	19 / 278 (6.83%)	10 / 251 (3.98%)	
occurrences (all)	28	12	
neutrophil count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	47 / 278 (16.91%)	30 / 251 (11.95%)	
occurrences (all)	84	51	
platelet count decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	59 / 278 (21.22%)	26 / 251 (10.36%)	
occurrences (all)	163	51	
weight decreased			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	14 / 278 (5.04%)	25 / 251 (9.96%)	
occurrences (all)	17	34	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	19 / 278 (6.83%)	8 / 251 (3.19%)	
occurrences (all)	23	9	
dysgeusia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	19 / 278 (6.83%)	9 / 251 (3.59%)	
occurrences (all)	22	11	
headache			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	18 / 278 (6.47%)	17 / 251 (6.77%)	
occurrences (all)	24	20	
neuropathy peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	40 / 278 (14.39%)	38 / 251 (15.14%)	
occurrences (all)	50	62	
neurotoxicity			
alternative dictionary used: MedDRA 23.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>paraesthesia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>peripheral sensory neuropathy</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>polyneuropathy</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>13 / 278 (4.68%)</p> <p>25</p> <p>24 / 278 (8.63%)</p> <p>34</p> <p>31 / 278 (11.15%)</p> <p>48</p> <p>9 / 278 (3.24%)</p> <p>13</p>	<p>15 / 251 (5.98%)</p> <p>30</p> <p>17 / 251 (6.77%)</p> <p>44</p> <p>29 / 251 (11.55%)</p> <p>35</p> <p>14 / 251 (5.58%)</p> <p>25</p>	
<p>Blood and lymphatic system disorders</p> <p>anaemia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>neutropenia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>thrombocytopenia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>107 / 278 (38.49%)</p> <p>204</p> <p>58 / 278 (20.86%)</p> <p>118</p> <p>99 / 278 (35.61%)</p> <p>296</p>	<p>38 / 251 (15.14%)</p> <p>56</p> <p>41 / 251 (16.33%)</p> <p>65</p> <p>28 / 251 (11.16%)</p> <p>42</p>	
<p>General disorders and administration site conditions</p> <p>asthenia</p> <p>alternative dictionary used: MedDRA 23.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>fatigue</p> <p>alternative dictionary used: MedDRA 23.0</p>	<p>76 / 278 (27.34%)</p> <p>151</p>	<p>45 / 251 (17.93%)</p> <p>105</p>	

subjects affected / exposed	105 / 278 (37.77%)	74 / 251 (29.48%)	
occurrences (all)	181	108	
injection site erythema			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	18 / 278 (6.47%)	0 / 251 (0.00%)	
occurrences (all)	18	0	
oedema peripheral			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	41 / 278 (14.75%)	22 / 251 (8.76%)	
occurrences (all)	49	25	
pyrexia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	56 / 278 (20.14%)	36 / 251 (14.34%)	
occurrences (all)	82	51	
Gastrointestinal disorders			
abdominal distension			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	18 / 278 (6.47%)	14 / 251 (5.58%)	
occurrences (all)	22	15	
abdominal pain			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	82 / 278 (29.50%)	58 / 251 (23.11%)	
occurrences (all)	114	82	
abdominal pain upper			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	20 / 278 (7.19%)	14 / 251 (5.58%)	
occurrences (all)	34	17	
ascites			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	28 / 278 (10.07%)	19 / 251 (7.57%)	
occurrences (all)	35	20	
constipation			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed	79 / 278 (28.42%)	59 / 251 (23.51%)	
occurrences (all)	93	70	
diarrhoea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	70 / 278 (25.18%)	71 / 251 (28.29%)	
occurrences (all)	104	101	
dyspepsia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	21 / 278 (7.55%)	14 / 251 (5.58%)	
occurrences (all)	23	16	
flatulence			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	14 / 278 (5.04%)	4 / 251 (1.59%)	
occurrences (all)	15	6	
nausea			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	126 / 278 (45.32%)	106 / 251 (42.23%)	
occurrences (all)	217	160	
stomatitis			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	27 / 278 (9.71%)	40 / 251 (15.94%)	
occurrences (all)	37	48	
vomiting			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	80 / 278 (28.78%)	69 / 251 (27.49%)	
occurrences (all)	122	106	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	17 / 278 (6.12%)	19 / 251 (7.57%)	
occurrences (all)	22	22	
dyspnoea			
alternative dictionary used: MedDRA 23.0			

subjects affected / exposed occurrences (all)	30 / 278 (10.79%) 41	15 / 251 (5.98%) 17	
Skin and subcutaneous tissue disorders pruritus alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) rash alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	15 / 278 (5.40%) 24 23 / 278 (8.27%) 34	8 / 251 (3.19%) 11 9 / 251 (3.59%) 10	
Psychiatric disorders insomnia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	14 / 278 (5.04%) 14	13 / 251 (5.18%) 13	
Musculoskeletal and connective tissue disorders back pain alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all)	37 / 278 (13.31%) 44	32 / 251 (12.75%) 39	
Metabolism and nutrition disorders decreased appetite alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) dehydration alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) hyperglycaemia alternative dictionary used: MedDRA 23.0 subjects affected / exposed occurrences (all) hypoalbuminaemia	97 / 278 (34.89%) 132 12 / 278 (4.32%) 22 14 / 278 (5.04%) 20	77 / 251 (30.68%) 100 14 / 251 (5.58%) 19 10 / 251 (3.98%) 11	

alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	20 / 278 (7.19%)	10 / 251 (3.98%)	
occurrences (all)	28	11	
hypokalaemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	21 / 278 (7.55%)	29 / 251 (11.55%)	
occurrences (all)	37	39	
hyponatraemia			
alternative dictionary used: MedDRA 23.0			
subjects affected / exposed	11 / 278 (3.96%)	16 / 251 (6.37%)	
occurrences (all)	15	21	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 June 2017	<ul style="list-style-type: none">- Inclusion and exclusion criteria updated.- Weight based dosing for treatment with pegilodecakin updated.- Updated when and how SAEs/ suspected unexpected serious adverse reactions (SUSARs) were captured.
19 July 2017	<ul style="list-style-type: none">- Inclusion and exclusion criteria updated.- Contraception use guideline revised.- Weight based dosing for treatment with pegilodecakin updated.- Reporting of serious adverse events updated and definition of SUSAR added.- Planned hospitalization not to be designated as an serious adverse event.
15 May 2018	<ul style="list-style-type: none">- Changes to the inclusion/exclusion criteria.- New strength of pegilodecakin added.- Pegilodecakin container closure system changed.
05 October 2018	<ul style="list-style-type: none">- Secondary objectives and endpoints added.- Study design was updated to allow continued access.- Inclusion criteria updated.- Censoring guidance for PFS changed.- Subgroup and sensitivity analysis plan added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported