Clinical trial results:
A Study of the Safety and Efficacy of the Combination of Gemcitabine and Docetaxel with MORAb-004 in Metastatic Soft Tissue Sarcoma

Summary

EudraCT number	2012-001399-12
Trial protocol	BE NL
Global end of trial date	02 August 2016

Results information

Result version number	v2 (current)
This version publication date	17 August 2019
First version publication date	20 April 2019
Version creation reason	• Correction of full data set Added description in the "Adverse events" section of "Adverse event reporting additional description".

Trial information

Trial identification

Sponsor protocol code	MORAb-004-203-STS

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01574716
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Morphotek (a subsidiary of Eisai Inc.)
Sponsor organisation address	210 Welsh Pool Road, Exton, United States, 19341
Public contact	Medical Information, Eisai Europe Ltd., +44 20 8600 1400, LMedInfo@eisai.net
Scientific contact	Medical Information, Eisai Europe Ltd., +44 20 8600 1400, LMedInfo@eisai.net

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	02 August 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 August 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the radiologic progression-free survival (PFS) of subjects treated with the combination of gemcitabine/docetaxel plus MORAb-004 versus gemcitabine/docetaxel plus placebo in subjects with metastatic soft tissue sarcoma (mSTS) in 4 defined subgroups:
1. Liposarcoma (excluding pure, well-differentiated sarcoma)
2. Leiomyosarcoma
3. Undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (UPS previously characterized as MFH)
4. Other STS, that is, subjects with a histologic diagnosis of high grade sarcoma not otherwise specified (NOS), angiosarcoma, synovial sarcoma, rhabdomyosarcoma, hemagiopericytoma/ solitary fibrous tumor, or other liposarcoma.

Protection of trial subjects:

This study was conducted in accordance with standard operating procedures (SOPs) of the sponsor (or designee), which are designed to ensure adherence to Good Clinical Practice (GCP) guidelines as required by the following: - Principles of the World Medical Association Declaration of Helsinki (World Medical Association, 2008) - International Council on Harmonisation (ICH) E6 Guideline for GCP (CPMP/ICH/135/95) of the European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products, International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Title 21 of the United States (US) Code of Federal Regulations (US 21 CFR) regarding clinical studies, including Part 50 and Part 56 concerning informed subject consent and Institutional Review Board (IRB) regulations and applicable sections of US 21 CFR Part 312 - European Good Clinical Practice Directive 2005/28/EC and Clinical Trial Directive 2001/20/EC for studies conducted within any European Union (EU) country. All suspected unexpected serious adverse reactions were reported, as required, to the Competent Authorities of all involved EU member states. - Article 14, Paragraph 3, and Article 80-2 of the Pharmaceutical Affairs Law (Law No. 145, 1960) for studies conducted in Japan, in addition to Japan’s GCP Subject Information and Informed Consent.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	07 August 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	United States: 186

Country: Number of subjects enrolled	Australia: 16
Worldwide total number of subjects	225
EEA total number of subjects	23

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)	166
From 65 to 84 years	59
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects took part in the study at 31 investigative sites in the United States, Australia, Italy, Netherlands, France and Belgium from 07 August 2012 to 02 August 2016.

Pre-assignment

Screening details:

In Part 1, a total of 16 subjects were enrolled and treated in the study. A total of 225 subjects were screened for entry into Part 2 of the study. Of these 225 subjects, 46 were screen failures and 209 were randomized into the study, of which 207 subjects were treated.

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, Carer

Blinding implementation details:

Part 1 of the study was an open-label, standard 3-plus-3 dose escalation of MORAb-004 (4, 6, and 8 milligram per kilogram [mg/kg]) in combination with gemcitabine/docetaxel (900 milligram per square meter [mg/m^2] and 75 mg/m^2, respectively) infusion. Part 2 of the study was a randomized, double-blind, placebo-controlled study of 8 mg/kg MORAb-004 in combination with gemcitabine/docetaxel infusion versus placebo in combination with gemcitabine/docetaxel infusion.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: MORAb-004 4.0 mg/kg + Gemcitabine/Docetaxel

Arm description:

Subjects received MORAb-004 4 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	MORAb-004
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MORAb-004 4 mg/kg, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Arm title	Part 1: MORAb-004 6.0 mg/kg + Gemcitabine/Docetaxel

Arm description:

Subjects received MORAb-004 6 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	MORAb-004
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MORAb-004 6 mg/kg, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Arm title	Part 1: MORAb-004 8.0 mg/kg + Gemcitabine/Docetaxel

Arm description:

Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	MORAb-004
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Arm title	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel

Arm description:

Subjects received MORAb-004 8.0 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	MORAb-004
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles).

Arm title	Part 2: Placebo + Gemcitabine/Docetaxel

Arm description:

Subjects received normal saline (0.9 percent [%] sodium chloride), infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). Normal saline (0.9% sodium chloride) was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

Subjects received normal saline (0.9% sodium chloride), infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle, until disease progression (approximately 28 cycles). Normal saline (0.9% sodium chloride) was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 of each 21-day treatment cycle.

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle.

Number of subjects in period 1	Part 1: MORAb-004 4.0 mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 6.0 mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 8.0 mg/kg + Gemcitabine/Docetaxel
Started	3	4	9
Completed	0	0	0
Not completed	3	4	9
Consent withdrawn by subject	-	2	-
Brain metastases	-	-	-
Death	3	1	8
Discontinuation by study sponsor	-	-	1
Lost to follow-up	-	1	-
Progressive disease	-	-	-

Number of subjects in period 1	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel
Started	139	70
Completed	2	0
Not completed	137	70
Consent withdrawn by subject	5	4
Brain metastases	1	-
Death	76	35
Discontinuation by study sponsor	51	31
Lost to follow-up	3	-
Progressive disease	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Part 1: MORAb-004 4.0 mg/kg + Gemcitabine/Docetaxel
Reporting group description:	
Subjects received MORAb-004 4 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.	
Reporting group title	Part 1: MORAb-004 6.0 mg/kg + Gemcitabine/Docetaxel
Reporting group description:	
Subjects received MORAb-004 6 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.	
Reporting group title	Part 1: MORAb-004 8.0 mg/kg + Gemcitabine/Docetaxel
Reporting group description:	
Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.	
Reporting group title	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel
Reporting group description:	
Subjects received MORAb-004 8.0 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.	
Reporting group title	Part 2: Placebo + Gemcitabine/Docetaxel
Reporting group description:	
Subjects received normal saline (0.9 percent [%] sodium chloride), infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). Normal saline (0.9% sodium chloride) was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.	

Reporting group values	Part 1: MORAb-004 4.0 mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 6.0 mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 8.0 mg/kg + Gemcitabine/Docetaxel
Number of subjects	3	4	9
Age categorical Units: Subjects			
Adults (18-64 years)	3	3	8
From 65-84 years	0	1	1
Gender categorical Units: Subjects			
Female	2	2	3
Male	1	2	6
Race characteristic Units: Subjects			
White	1	3	8

Black or African American	1	1	0
Asian	1	0	1
Chinese	0	0	0
American Indian or Alaskan Native	0	0	0
Other	0	0	0
Ethnicity characteristic Units: Subjects			
Hispanic or Latino	1	0	2
Non-Hispanic or Non-Latino	2	4	7
Not Permitted by Regulatory Authority	0	0	0

Reporting group values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel	Total
Number of subjects	139	70	225
Age categorical Units: Subjects			
Adults (18-64 years)	103	49	166
From 65-84 years	36	21	59
Gender categorical Units: Subjects			
Female	63	32	102
Male	76	38	123
Race characteristic Units: Subjects			
White	116	57	185
Black or African American	12	9	23
Asian	7	2	11
Chinese	0	2	2
American Indian or Alaskan Native	1	0	1
Other	3	0	3
Ethnicity characteristic Units: Subjects			
Hispanic or Latino	18	8	29
Non-Hispanic or Non-Latino	119	61	193
Not Permitted by Regulatory Authority	2	1	3

End points

End points reporting groups

Reporting group title	Part 1: MORAb-004 4.0 mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 4 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 1: MORAb-004 6.0 mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 6 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 1: MORAb-004 8.0 mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 8.0 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 2: Placebo + Gemcitabine/Docetaxel

Reporting group description:

Subjects received normal saline (0.9 percent [%] sodium chloride), infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). Normal saline (0.9% sodium chloride) was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Primary: Part 2: Radiologic Progression-free Survival (PFS)

End point title	Part 2: Radiologic Progression-free Survival (PFS)[1]

End point description:

PFS was defined as the time (in weeks) from the date of randomization to the date of first observation of disease progression according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1) or date of death, regardless of the cause. The intention-to-treat (ITT) population consisted of all randomized subjects and were analyzed according to the treatment assigned by the interactive randomization system (IxRS).

End point type	Primary

End point timeframe:

From date of first dose until date of first observation of disease progression, or death due to any cause (up to approximately 3 years)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2:

MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: Weeks				
median (confidence interval 95%)	18.7 (11.6 to 27.4)	24.1 (11.1 to 36.1)		

Statistical analyses

Statistical analysis title	Part 2: Radiologic Progression-free Survival (PFS)
Comparison groups	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel v Part 2: Placebo + Gemcitabine/Docetaxel
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6562 [2]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.5

Notes:

[2] - Two-sided log-rank test.

Secondary: Part 2: Symptomatic Progression-free Survival

End point title	Part 2: Symptomatic Progression-free Survival[3]

End point description:

PFS including symptomatic progression was defined as the time (in weeks) from the date of randomization to the date of the first observation of disease progression according to RECIST 1.1, symptomatic progression, or death due to any cause. The ITT population consisted of all randomized subjects and were analyzed according to treatment assigned by the IxRS.

End point type	Secondary

End point timeframe:

From date of first dose until date of first observation of disease progression, symptomatic progression, or death due to any cause (up to approximately 3 years)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: Weeks				
median (confidence interval 95%)	18.1 (11.3 to 24)	24 (10.7 to 36.1)		

Statistical analyses

Statistical analysis title	Symptomatic Progression-free Survival
Comparison groups	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel v Part 2: Placebo + Gemcitabine/Docetaxel
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4469 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.57

Notes:

[4] - Two-sided log-rank test.

Secondary: Part 2: Overall Survival (OS)

End point title	Part 2: Overall Survival (OS)[5]

End point description:

OS was defined as the time (in months) from the date of randomization to the date of death, regardless of the cause. The ITT Population consisted of all randomized subjects and were analyzed according to treatment assigned by the IxRS. Here "99999" refers to the upper limit of confidence interval (CI), which was not estimable since high number of subjects were censored from analysis and therefore we have added 99999 as space-fillers.

End point type	Secondary

End point timeframe:

From date of first dose until date of death from any cause (up to approximately 3.5 years)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: Months				
median (confidence interval 95%)	18.3 (16.2 to 21.1)	21.1 (14.2 to 99999)		

Statistical analyses

Statistical analysis title	Overall Survival
Comparison groups	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel v Part 2: Placebo + Gemcitabine/Docetaxel
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3153 [6]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.83

Notes:

[6] - Two-sided log-rank test.

Secondary: Part 2: Overall Response Rate (ORR)

End point title	Part 2: Overall Response Rate (ORR)[7]

End point description:

ORR was defined as the percentage of subjects with either a complete response (CR) or a partial response (PR) based on RECIST 1.1. CR was defined as disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (>) 10 millimeter (mm). PR was defined as at least a 30 percent (%) decrease in sum of diameters of target lesions, taking as reference the baseline sum of diameters. The ITT Population consisted of all randomized participants and were analyzed according to treatment assigned by the IxRS.

End point type	Secondary

End point timeframe:

From date of first dose until disease progression (up to approximately 3.6 years)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: percentage of subjects				
number (not applicable)	19.4	20.0		

Statistical analyses

Statistical analysis title	Part 2: ORR

Statistical analysis description:

Difference = (MORAb 8.0 mg/kg + Gemcitabine/Docetaxel) minus (Placebo + Gemcitabine/Docetaxel). Confidence interval based on a normal approximation to the binomial distribution.

Comparison groups	Part 2: Placebo + Gemcitabine/Docetaxel v Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1 [8]
Method	2-sided exact p-value
Parameter estimate	Difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	10.9

Notes:

[8] - Two-sided log-rank test.

Secondary: Part 2: Radiologic Progression-free Survival Rate (PFR)

End point title	Part 2: Radiologic Progression-free Survival Rate (PFR)[9]

End point description:

Radiologic progression-free survival rate was defined as the percentage of subjects achieving radiologic PFS at the pre-specified time points. The ITT Population consisted of all randomized subjects and were analyzed according to treatment assigned by the IxRS.

End point type	Secondary

End point timeframe:

Weeks 12, 24, 48 and 52

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: percentage of subjects				
number (not applicable)				
12 weeks	57.6	61.8		
24 weeks	43.3	51.0		
48 weeks	24.5	25.2		
52 weeks	20.8	21.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Subjects who had Relationship Between MORAb-004 Exposures and Biomarker Levels

End point title	Part 2: Number of Subjects who had Relationship Between MORAb-004 Exposures and Biomarker Levels[10]

End point description:

The ITT Population consisted of all randomized subjects and were analyzed according to treatment assigned by the IxRS.

End point type	Secondary

End point timeframe:

Up to approximately 3 years

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be analyzed for the following reporting groups: Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel and Part 2: Placebo +Gemcitabine/Docetaxel.

End point values	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	70		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From date of first dose until 45 days after last dose of study drug (approximately up to 4 years).

Adverse event reporting additional description:

Part 2, MORAb-004 8.0mg/kg + Gemcitabine/Docetaxel: 2 subjects discontinued prior to treatment. Part 2, Placebo + Gemcitabine/Docetaxel: 3 subjects randomized but received MORAb are counted in "Part 2, MORAb-004 8.0mg/kg + Gemcitabine/Docetaxel" arm.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Part 1: MORAb-004 4.0mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 4 milligram per kilogram (mg/kg), infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 milligram per square meter (mg/m^2), infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 1: MORAb-004 6.0mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 6 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 1: MORAb-004 8.0mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 8 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle until disease progression (approximately 28 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel

Reporting group description:

Subjects received MORAb-004 8.0 mg/kg, infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). MORAb-004 was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Reporting group title	Part 2: Placebo + Gemcitabine/Docetaxel

Reporting group description:

Subjects received normal saline (0.9 % sodium chloride), infusion, intravenously on Days 1 and 8 in combination with gemcitabine 900 mg/m^2, infusion, intravenously on Days 1 and 8 and docetaxel 75 mg/m^2, infusion, intravenously on Day 8 of each 21-day treatment cycle for until disease progression (approximately 31 cycles). Normal saline (0.9% sodium chloride) was administered after the administration of gemcitabine on Day 1 and after the administration of gemcitabine/docetaxel on Day 8 in each 21-day treatment cycle.

Serious adverse events	Part 1: MORAb-004 4.0mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 6.0mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 8.0mg/kg + Gemcitabine/Docetaxel
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	1 / 4 (25.00%)	9 / 9 (100.00%)
number of deaths (all causes)	3	1	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Malignant Pleural Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Metastases To Central Nervous System			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Tumour Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Vena cava thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Capillary leak syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Generalised Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Infusion Site Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Mucosal Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Non-Cardiac Chest Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Haemothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Dyspnoea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Investigations			
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 Creatine Phosphokinase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Platelet Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Clavicle Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Femur Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Rib Fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Cardiac disorders			
Pericardial Effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Atrial Flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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

Atrial Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Cardiac Arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Diastolic Dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Sinus Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Cardiac Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Embolic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Lethargy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Transient global amnesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 9 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic Uraemic Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Abdominal Hernia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Pancreatic Cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Ileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Intussusception			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hepatobiliary disorders			
Hepatic Failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hepatotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Portal Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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

Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Musculoskeletal and connective tissue disorders			
Pain In Extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Groin Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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

Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Campylobacter Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Corona Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Enterocolitis Infectious			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Escherichia Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Liver Abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Lobar Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Neutropenic Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Pneumocystis Jiroveci Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Pneumocystis Jiroveci Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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 Tract Infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Soft Tissue Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Primary Atypical			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Wound Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (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
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel	
Total subjects affected by serious adverse events			
subjects affected / exposed	106 / 140 (75.71%)	45 / 67 (67.16%)	
number of deaths (all causes)	76	35	
number of deaths resulting from adverse events	4	3	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer Pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant Pleural Effusion			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases To Central Nervous System			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour Pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Capillary leak syndrome			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	7 / 10	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised Oedema			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion Site Extravasation			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal Inflammation			

subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema Peripheral			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine Release Syndrome			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pulmonary oedema			
subjects affected / exposed	3 / 140 (2.14%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pulmonary haemorrhage			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 140 (1.43%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	4 / 140 (2.86%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	2 / 140 (1.43%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural Haemorrhage			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	3 / 140 (2.14%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	3 / 8	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemothorax			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			

subjects affected / exposed	2 / 140 (1.43%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	6 / 140 (4.29%)	3 / 67 (4.48%)	
occurrences causally related to treatment / all	2 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
White Blood Cell Count Decreased			
subjects affected / exposed	2 / 140 (1.43%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	1 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatine Phosphokinase Increased			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood Creatinine Increased			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil Count Decreased			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Platelet Count Decreased			
subjects affected / exposed	1 / 140 (0.71%)	3 / 67 (4.48%)	
occurrences causally related to treatment / all	7 / 7	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle Fracture			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur Fracture			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion Related Reaction			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib Fracture			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Pericardial Effusion			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Atrial Flutter			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial Thrombosis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Arrest			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Diastolic Dysfunction			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus Tachycardia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac Failure			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Memory impairment			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient global amnesia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 140 (3.57%)	4 / 67 (5.97%)	
occurrences causally related to treatment / all	3 / 9	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			

subjects affected / exposed	3 / 140 (2.14%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	2 / 140 (1.43%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	2 / 140 (1.43%)	3 / 67 (4.48%)	
occurrences causally related to treatment / all	1 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic Uraemic Syndrome			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 140 (2.86%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	2 / 4	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	3 / 140 (2.14%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Hernia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 140 (0.71%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Constipation			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal Pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic Cyst			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal Pain			
subjects affected / exposed	0 / 140 (0.00%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			

subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic Failure			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatotoxicity			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal Vein Thrombosis			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Renal failure acute			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Renal failure			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Pain In Extremity			
subjects affected / exposed	2 / 140 (1.43%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back Pain			
subjects affected / exposed	1 / 140 (0.71%)	3 / 67 (4.48%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin Pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Myositis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	8 / 140 (5.71%)	3 / 67 (4.48%)	
occurrences causally related to treatment / all	1 / 8	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	7 / 140 (5.00%)	6 / 67 (8.96%)	
occurrences causally related to treatment / all	2 / 7	1 / 6	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lung Infection			
subjects affected / exposed	3 / 140 (2.14%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary Tract Infection			
subjects affected / exposed	3 / 140 (2.14%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 140 (1.43%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter Gastroenteritis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona Virus Infection			

subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis Infectious			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia Sepsis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Abscess			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobar Pneumonia			
subjects affected / exposed	1 / 140 (0.71%)	2 / 67 (2.99%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neutropenic Sepsis			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis Jiroveci Infection			
subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	1 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis Jiroveci Pneumonia			

subjects affected / exposed	1 / 140 (0.71%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory Tract Infection			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft Tissue Infection			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia Primary Atypical			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound Infection			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	6 / 140 (4.29%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	2 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			

subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	0 / 140 (0.00%)	1 / 67 (1.49%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1: MORAb-004 4.0mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 6.0mg/kg + Gemcitabine/Docetaxel	Part 1: MORAb-004 8.0mg/kg + Gemcitabine/Docetaxel
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot Flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	3 / 4 (75.00%)	6 / 9 (66.67%)
occurrences (all)	3	6	7

Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	4 / 9 (44.44%)
occurrences (all)	2	1	6
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	2 / 9 (22.22%)
occurrences (all)	1	5	6
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter Site Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Dyspnoea Exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Hiccups			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oropharyngeal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	4
Platelet Count Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood Albumin Decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	3 / 9 (33.33%)
occurrences (all)	1	2	3
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	2
Paraesthesia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Loss of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	8 / 9 (88.89%)
occurrences (all)	3	2	20
Thrombocytopenia			
subjects affected / exposed	3 / 3 (100.00%)	0 / 4 (0.00%)	8 / 9 (88.89%)
occurrences (all)	8	0	29
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	4 / 9 (44.44%)
occurrences (all)	4	6	10
Leukopenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Ear and labyrinth disorders			
Deafness Unilateral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Tinnitus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vision Blurred			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	5 / 9 (55.56%)
occurrences (all)	3	1	5
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	2 / 9 (22.22%)
occurrences (all)	2	1	3
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dental Caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peptic ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
Rash			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-Papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Nail disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract obstruction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	3 / 4 (75.00%)	1 / 9 (11.11%)
occurrences (all)	1	3	1
Pain in extremity			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 4 (75.00%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bone Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Metatarsalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Muscle twitching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pain in jaw			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Oral Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3

Staphylococcal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part 2: MORAb 8.0 mg/kg + Gemcitabine/Docetaxel	Part 2: Placebo + Gemcitabine/Docetaxel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	140 / 140 (100.00%)	66 / 67 (98.51%)	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	17 / 140 (12.14%)	2 / 67 (2.99%)	
occurrences (all)	32	3	
Hot Flush			
subjects affected / exposed	9 / 140 (6.43%)	0 / 67 (0.00%)	
occurrences (all)	11	0	
Hypotension			
subjects affected / exposed	7 / 140 (5.00%)	7 / 67 (10.45%)	
occurrences (all)	7	7	
Flushing			
subjects affected / exposed	7 / 140 (5.00%)	4 / 67 (5.97%)	
occurrences (all)	7	6	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	103 / 140 (73.57%)	44 / 67 (65.67%)	
occurrences (all)	154	64	
Pyrexia			
subjects affected / exposed	51 / 140 (36.43%)	17 / 67 (25.37%)	
occurrences (all)	85	27	
Oedema peripheral			
subjects affected / exposed	59 / 140 (42.14%)	29 / 67 (43.28%)	
occurrences (all)	100	44	
Chills			
subjects affected / exposed	28 / 140 (20.00%)	3 / 67 (4.48%)	
occurrences (all)	42	4	
Influenza like illness			
subjects affected / exposed	15 / 140 (10.71%)	2 / 67 (2.99%)	
occurrences (all)	20	4	
Mucosal Inflammation			
subjects affected / exposed	12 / 140 (8.57%)	6 / 67 (8.96%)	
occurrences (all)	16	7	

Pain			
subjects affected / exposed	11 / 140 (7.86%)	4 / 67 (5.97%)	
occurrences (all)	19	5	
Non-Cardiac Chest Pain			
subjects affected / exposed	7 / 140 (5.00%)	1 / 67 (1.49%)	
occurrences (all)	8	1	
Asthenia			
subjects affected / exposed	7 / 140 (5.00%)	4 / 67 (5.97%)	
occurrences (all)	16	4	
Chest Pain			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	9	3	
Catheter Site Rash			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Early satiety			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	11 / 140 (7.86%)	5 / 67 (7.46%)	
occurrences (all)	11	5	
Dyspnoea			
subjects affected / exposed	41 / 140 (29.29%)	18 / 67 (26.87%)	
occurrences (all)	56	23	
Cough			
subjects affected / exposed	42 / 140 (30.00%)	23 / 67 (34.33%)	
occurrences (all)	56	27	
Epistaxis			
subjects affected / exposed	18 / 140 (12.86%)	10 / 67 (14.93%)	
occurrences (all)	22	14	
Pleural effusion			
subjects affected / exposed	10 / 140 (7.14%)	3 / 67 (4.48%)	
occurrences (all)	10	3	
Dyspnoea Exertional			

subjects affected / exposed	12 / 140 (8.57%)	7 / 67 (10.45%)	
occurrences (all)	12	7	
Haemoptysis			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Hiccups			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	4 / 140 (2.86%)	5 / 67 (7.46%)	
occurrences (all)	6	5	
Oropharyngeal discomfort			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	24 / 140 (17.14%)	12 / 67 (17.91%)	
occurrences (all)	25	12	
Anxiety			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	7	2	
Depression			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	7	3	
Investigations			
Alanine Aminotransferase Increased			

subjects affected / exposed	31 / 140 (22.14%)	12 / 67 (17.91%)	
occurrences (all)	43	20	
Platelet Count Decreased			
subjects affected / exposed	20 / 140 (14.29%)	15 / 67 (22.39%)	
occurrences (all)	41	67	
Aspartate Aminotransferase Increased			
subjects affected / exposed	16 / 140 (11.43%)	8 / 67 (11.94%)	
occurrences (all)	18	15	
Blood Alkaline Phosphatase Increased			
subjects affected / exposed	13 / 140 (9.29%)	7 / 67 (10.45%)	
occurrences (all)	16	8	
Neutrophil Count Decreased			
subjects affected / exposed	13 / 140 (9.29%)	9 / 67 (13.43%)	
occurrences (all)	14	31	
White Blood Cell Count Decreased			
subjects affected / exposed	11 / 140 (7.86%)	10 / 67 (14.93%)	
occurrences (all)	33	17	
Blood Creatinine Increased			
subjects affected / exposed	10 / 140 (7.14%)	4 / 67 (5.97%)	
occurrences (all)	11	7	
Blood Albumin Decreased			
subjects affected / exposed	8 / 140 (5.71%)	4 / 67 (5.97%)	
occurrences (all)	9	5	
Lymphocyte count decreased			
subjects affected / exposed	8 / 140 (5.71%)	8 / 67 (11.94%)	
occurrences (all)	24	28	
Weight decreased			
subjects affected / exposed	8 / 140 (5.71%)	2 / 67 (2.99%)	
occurrences (all)	9	2	
Blood calcium decreased			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	9	2	
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	10 / 140 (7.14%)	1 / 67 (1.49%)	
occurrences (all)	10	11	
Contusion			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Tooth fracture			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	57 / 140 (40.71%)	13 / 67 (19.40%)	
occurrences (all)	78	20	
Dysgeusia			
subjects affected / exposed	31 / 140 (22.14%)	15 / 67 (22.39%)	
occurrences (all)	44	17	
Dizziness			
subjects affected / exposed	16 / 140 (11.43%)	10 / 67 (14.93%)	
occurrences (all)	19	12	
Neuropathy peripheral			
subjects affected / exposed	16 / 140 (11.43%)	16 / 67 (23.88%)	
occurrences (all)	20	16	
Paraesthesia			
subjects affected / exposed	14 / 140 (10.00%)	7 / 67 (10.45%)	
occurrences (all)	21	7	
Peripheral sensory neuropathy			
subjects affected / exposed	8 / 140 (5.71%)	5 / 67 (7.46%)	
occurrences (all)	8	5	
Loss of consciousness			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Neuralgia			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Hyperaesthesia			

subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	85 / 140 (60.71%)	37 / 67 (55.22%)	
occurrences (all)	138	55	
Thrombocytopenia			
subjects affected / exposed	56 / 140 (40.00%)	28 / 67 (41.79%)	
occurrences (all)	151	80	
Neutropenia			
subjects affected / exposed	32 / 140 (22.86%)	15 / 67 (22.39%)	
occurrences (all)	56	28	
Leukopenia			
subjects affected / exposed	20 / 140 (14.29%)	11 / 67 (16.42%)	
occurrences (all)	30	23	
Ear and labyrinth disorders			
Deafness Unilateral			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Ear Pain			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	8 / 140 (5.71%)	6 / 67 (8.96%)	
occurrences (all)	10	6	
Conjunctivitis			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Vision Blurred			

subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	75 / 140 (53.57%)	34 / 67 (50.75%)	
occurrences (all)	125	49	
Constipation			
subjects affected / exposed	54 / 140 (38.57%)	25 / 67 (37.31%)	
occurrences (all)	73	34	
Abdominal pain			
subjects affected / exposed	11 / 140 (7.86%)	15 / 67 (22.39%)	
occurrences (all)	12	17	
Diarrhoea			
subjects affected / exposed	61 / 140 (43.57%)	24 / 67 (35.82%)	
occurrences (all)	112	36	
Vomiting			
subjects affected / exposed	38 / 140 (27.14%)	11 / 67 (16.42%)	
occurrences (all)	50	17	
Stomatitis			
subjects affected / exposed	17 / 140 (12.14%)	5 / 67 (7.46%)	
occurrences (all)	24	6	
Dyspepsia			
subjects affected / exposed	10 / 140 (7.14%)	2 / 67 (2.99%)	
occurrences (all)	15	2	
Abdominal Pain Upper			
subjects affected / exposed	9 / 140 (6.43%)	6 / 67 (8.96%)	
occurrences (all)	13	6	
Dry mouth			
subjects affected / exposed	8 / 140 (5.71%)	5 / 67 (7.46%)	
occurrences (all)	8	8	
Gastrooesophageal reflux disease			
subjects affected / exposed	8 / 140 (5.71%)	4 / 67 (5.97%)	
occurrences (all)	8	4	
Dental Caries			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	

Flatulence			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Oral pain			
subjects affected / exposed	1 / 140 (0.71%)	4 / 67 (5.97%)	
occurrences (all)	2	4	
Peptic ulcer			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	48 / 140 (34.29%)	21 / 67 (31.34%)	
occurrences (all)	52	21	
Rash			
subjects affected / exposed	30 / 140 (21.43%)	23 / 67 (34.33%)	
occurrences (all)	46	33	
Pruritus			
subjects affected / exposed	20 / 140 (14.29%)	3 / 67 (4.48%)	
occurrences (all)	24	3	
Rash Maculo-Papular			
subjects affected / exposed	12 / 140 (8.57%)	1 / 67 (1.49%)	
occurrences (all)	14	1	
Dry Skin			
subjects affected / exposed	10 / 140 (7.14%)	5 / 67 (7.46%)	
occurrences (all)	11	5	
Erythema			
subjects affected / exposed	10 / 140 (7.14%)	4 / 67 (5.97%)	
occurrences (all)	12	5	
Hyperhidrosis			

subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Nail disorder			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Skin exfoliation			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Urinary tract obstruction			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	21 / 140 (15.00%)	13 / 67 (19.40%)	
occurrences (all)	26	14	
Pain in extremity			
subjects affected / exposed	25 / 140 (17.86%)	13 / 67 (19.40%)	
occurrences (all)	29	14	
Arthralgia			
subjects affected / exposed	21 / 140 (15.00%)	15 / 67 (22.39%)	
occurrences (all)	25	26	
Myalgia			
subjects affected / exposed	34 / 140 (24.29%)	13 / 67 (19.40%)	
occurrences (all)	48	18	
Bone Pain			

subjects affected / exposed	20 / 140 (14.29%)	10 / 67 (14.93%)	
occurrences (all)	21	10	
Musculoskeletal pain			
subjects affected / exposed	14 / 140 (10.00%)	5 / 67 (7.46%)	
occurrences (all)	16	6	
Musculoskeletal chest pain			
subjects affected / exposed	8 / 140 (5.71%)	2 / 67 (2.99%)	
occurrences (all)	9	2	
Groin pain			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Metatarsalgia			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Muscle twitching			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	9 / 140 (6.43%)	4 / 67 (5.97%)	
occurrences (all)	10	4	
Upper Respiratory Tract Infection			
subjects affected / exposed	17 / 140 (12.14%)	3 / 67 (4.48%)	
occurrences (all)	21	3	
Urinary tract infection			
subjects affected / exposed	13 / 140 (9.29%)	4 / 67 (5.97%)	
occurrences (all)	17	6	
Pneumonia			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	7	2	

Nasopharyngitis			
subjects affected / exposed	7 / 140 (5.00%)	3 / 67 (4.48%)	
occurrences (all)	10	3	
Sinusitis			
subjects affected / exposed	7 / 140 (5.00%)	2 / 67 (2.99%)	
occurrences (all)	8	2	
Diverticulitis			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Oral Candidiasis			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Staphylococcal skin infection			
subjects affected / exposed	0 / 140 (0.00%)	0 / 67 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	43 / 140 (30.71%)	16 / 67 (23.88%)	
occurrences (all)	62	20	
Hypokalaemia			
subjects affected / exposed	19 / 140 (13.57%)	7 / 67 (10.45%)	
occurrences (all)	27	8	
Hyperglycaemia			
subjects affected / exposed	22 / 140 (15.71%)	4 / 67 (5.97%)	
occurrences (all)	34	6	
Dehydration			

subjects affected / exposed	12 / 140 (8.57%)	4 / 67 (5.97%)	
occurrences (all)	17	5	
Hypoalbuminaemia			
subjects affected / exposed	10 / 140 (7.14%)	2 / 67 (2.99%)	
occurrences (all)	13	2	
Hypomagnesaemia			
subjects affected / exposed	8 / 140 (5.71%)	2 / 67 (2.99%)	
occurrences (all)	10	2	
Hyponatraemia			
subjects affected / exposed	8 / 140 (5.71%)	1 / 67 (1.49%)	
occurrences (all)	11	1	
Hypocalcaemia			
subjects affected / exposed	7 / 140 (5.00%)	5 / 67 (7.46%)	
occurrences (all)	8	6	
Increased appetite			
subjects affected / exposed	1 / 140 (0.71%)	0 / 67 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 June 2012	Updated the inclusion and exclusion criteria, specified subjects with prior pelvic irradiation were to begin G/D therapy with a 25% dose reduction (per FDA recommendation), clarified that the MRP2D dose administration, added language to define the circumstances under which an extension of the study would be implemented.
19 April 2013	Added additional cohort (Cohort 4) of subjects to re-escalate to 8 mg/kg in Part 1 of the study, amended dose modifications in response to gemcitabine- or docetaxel-related adverse reactions.
20 August 2013	Updated the secondary objective and exploratory objectives, updated the inclusion criteria, updated the cohort status to indicate that a fourth cohort was opened and reescalated to 8 mg/kg, updated the enrollment number, updated the biomarker.
06 May 2014	Updated assay for serum drug concentrations was changed from enzyme-linked immunosorbent assay to ECLIA, updated the definition of DLT, updated premedication language and concomitant medication guidance and clarified dosing language of the study drug.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported