Clinical trial results:
Phase 3 Randomized Study of DS-1062a Versus Docetaxel in Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer (TROPION-LUNG01)

Summary

EudraCT number	2020-004643-80
Trial protocol	FR HU DE BE NL CZ IT
Global end of trial date	

Results information

Result version number	v1 (current)
This version publication date	09 August 2025
First version publication date	09 August 2025

Trial information

Trial identification

Sponsor protocol code	DS1062-A-U301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04656652
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Daiichi Sankyo Inc.
Sponsor organisation address	211 Mt. Airy Rd, Basking Ridge, United States, 07920
Public contact	Global Clinical Director, Daiichi Sankyo Inc., 07920 9089926400, CTRinfo_us@daiichisankyo.com
Scientific contact	Global Clinical Director, Daiichi Sankyo Inc, 07920 9089926400, CTRinfo_us@daiichisankyo.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	10 May 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 May 2024
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the efficacy of DS-1062a with that of docetaxel, as measured by PFS and OS, for subjects with NSCLC without actionable genomic alterations previously treated with platinum-based chemotherapy and an α-PD- 1/α-PD-L1 monoclonal antibody

Protection of trial subjects:

The study protocol, amendments, the informed consent form(s) (ICF[s]), and information sheets were approved by the appropriate and applicable Independent Ethics Committees (IECs) or Institutional Review Boards (IRBs). The study was conducted in compliance with the protocol, the ethical principles that have their origin in the Declaration of Helsinki, the International Council for Harmonisation (ICH) consolidated Guideline E6 for Good Clinical Practice (GCP) (CPMP/ICH/135/95), and applicable regulatory requirement(s).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 December 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	United States: 50
Country: Number of subjects enrolled	Argentina: 4
Country: Number of subjects enrolled	China: 13
Country: Number of subjects enrolled	Japan: 107
Country: Number of subjects enrolled	Korea, Republic of: 92
Country: Number of subjects enrolled	Singapore: 4
Country: Number of subjects enrolled	Taiwan: 15
Country: Number of subjects enrolled	Belgium: 12
Country: Number of subjects enrolled	Czechia: 4
Country: Number of subjects enrolled	France: 96
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Hungary: 1
Country: Number of subjects enrolled	Italy: 21
Country: Number of subjects enrolled	Netherlands: 19
Country: Number of subjects enrolled	Poland: 16
Country: Number of subjects enrolled	Russian Federation: 16
Country: Number of subjects enrolled	Spain: 88

Country: Number of subjects enrolled	Switzerland: 5
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Australia: 15
Worldwide total number of subjects	604
EEA total number of subjects	265

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)	317
From 65 to 84 years	285
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

A total of 605 participants , including 1 participant who was randomized twice, were randomized to the study in Europe, Asia, North America, South
America, and Australia.

Pre-assignment

Screening details:

811 participants were screened for the study, in which 604 participants were randomized and included in the Full Analysis Set.

Period 1

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

Blinding implementation details:

This study was open-label.

Arms

Are arms mutually exclusive?	Yes
Arm title	DS-1062a 6.0 mg/kg

Arm description:

Participants were randomized to receive 6.0 mg/kg of DS-1062a.

Arm type	Experimental
Investigational medicinal product name	Datopotamab deruxtecan
Investigational medicinal product code	
Other name	Datopotamab deruxtecan, Dato-DXd, DS1062a
Pharmaceutical forms	Powder for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants were randomized to receive 6.0 mg/kg of DS-1062a.

Arm title	Docetaxel 75 mg/m^2

Arm description:

Participants were randomized to receive 75 mg/m^2 docetaxel.

Arm type	Active comparator
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Intravenous use

Dosage and administration details:

Participants were randomized to receive 75 mg/m^2 docetaxel.

Number of subjects in period 1	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2
Started	299	305
Completed	68	62
Not completed	231	243
Adverse event, serious fatal	213	212
Consent withdrawn by subject	15	29
Other	1	-
Lost to follow-up	2	2

Baseline characteristics

Reporting groups	
Reporting group title	DS-1062a 6.0 mg/kg
Reporting group description:	
Participants were randomized to receive 6.0 mg/kg of DS-1062a.	
Reporting group title	Docetaxel 75 mg/m^2
Reporting group description:	
Participants were randomized to receive 75 mg/m^2 docetaxel.	

Reporting group values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2	Total
Number of subjects	299	305	604
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	62.7	62.6	
standard deviation	± 9.09	± 10.28	-
Gender categorical Units: Subjects			
Female	116	95	211
Male	183	210	393
Age categorical Units: Subjects			
<= 18 years	0	0	0
Between 18 and 65	162	155	317
>= 65 years	137	150	287
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	1	0	1
Asian	121	120	241
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	4	10
White	123	126	249
Other	42	47	89
Unknown or Not Reported	6	8	14

End points

End points reporting groups

Reporting group title	DS-1062a 6.0 mg/kg
Reporting group description:	
Participants were randomized to receive 6.0 mg/kg of DS-1062a.	
Reporting group title	Docetaxel 75 mg/m^2
Reporting group description:	
Participants were randomized to receive 75 mg/m^2 docetaxel.	

Primary: Progression-free Survival (PFS) As Assessed by Blinded Independent Central Review (BICR) Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point title	Progression-free Survival (PFS) As Assessed by Blinded Independent Central Review (BICR) Per RECIST v1.1 Following DS-1062a Versus Docetaxel[1]
End point description:	
PFS is defined as the time from randomization to the earlier of the dates of the first documentation of radiographic progressive disease or death due to any cause.	
End point type	Primary
End point timeframe:	
From randomization until disease progression or death (whichever occurs first), up to approximately 27 months	

Notes:

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

End point values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	299	305		
Units: months				
median (confidence interval 95%)	4.4 (4.2 to 5.6)	3.7 (2.9 to 4.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Overall Survival (OS) Following DS-1062a Versus Docetaxel

End point title	Overall Survival (OS) Following DS-1062a Versus Docetaxel [2]
End point description:	
OS is defined as the time from randomization to the date of death due to any cause.	
End point type	Primary
End point timeframe:	
From randomization until date of death due to any cause, up to to approximately 38 months	

Notes:

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

End point values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	299	305		
Units: months				
median (standard deviation)	12.9 (± 11.0)	11.8 (± 10.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) As Assessed by Blinded Independent Central Review (BICR) and Investigator As Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point title	Duration of Response (DOR) As Assessed by Blinded Independent Central Review (BICR) and Investigator As Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point description:

DOR is defined as the time from the date of the first documentation of objective response (confirmed CR or confirmed PR) to the date of the first documentation of radiographic Progressive Disease or death due to any cause, whichever occurs first.

End point type	Secondary

End point timeframe:

From date of first objective response (CR or PR) to date of first radiographic disease progression or death due to any cause (whichever occurs first), up to approximately 43 months

End point values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	299	305		
Units: months				
median (confidence interval 95%)				
Assessed by Blinded Independent Central Review	7.1 (5.6 to 10.9)	5.6 (5.4 to 8.1)		
Assessed by Investigator	9.6 (6.7 to 11.1)	6.4 (5.1 to 8.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR) As Assessed by Blinded Independent

Central Review (BICR) and Investigator As Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point title	Objective Response Rate (ORR) As Assessed by Blinded Independent Central Review (BICR) and Investigator As Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point description:

ORR is defined as the proportion of subjects who achieved a best overall response (BOR) of complete response (CR) or partial response (PR), as assessed by BICR and investigator per RECIST v1.1.

End point type	Secondary

End point timeframe:

From randomization until disease progression or death (whichever occurs first), up to approximately 43 months

End point values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	299	305		
Units: participants				
Assessed by Blinded Independent Central Review	79	39		
Assessed by Investigator	74	44		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) As Assessed by Investigator Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point title	Progression-free Survival (PFS) As Assessed by Investigator Per RECIST v1.1 Following DS-1062a Versus Docetaxel

End point description:

PFS is defined as the time from randomization to the earlier of the dates of the first documentation of radiographic progressive disease or death due to any cause.

End point type	Secondary

End point timeframe:

From randomization until disease progression or death (whichever occurs first), up to approximately 43 months

End point values	DS-1062a 6.0 mg/kg	Docetaxel 75 mg/m^2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	299	305		
Units: months				
median (confidence interval 95%)	4.4 (4.2 to 5.5)	3.0 (2.8 to 4.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AE) were collected from the date of signing the informed consent form up to 28 days after last dose of the study drug, up 43 months.

Adverse event reporting additional description:

A Treatment-emergent adverse event (TEAE) is defined as an AE with a start or worsening date on or after the start date of study treatment until 35 days since date of last dose of study treatment. Adverse Events used Safety Analysis Set, while Mortality used Full Analysis Set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26

Reporting groups

Reporting group title	Docetaxel 75 mg/m^2

Reporting group description:

Participants were randomized to receive 75 mg/m^2 docetaxel.

Reporting group title	DS-1062a 6.0 mg/kg

Reporting group description:

Participants were randomized to receive 6.0 mg/kg of DS-1062a.

Serious adverse events	Docetaxel 75 mg/m^2	DS-1062a 6.0 mg/kg	
Total subjects affected by serious adverse events			
subjects affected / exposed	111 / 290 (38.28%)	92 / 297 (30.98%)	
number of deaths (all causes)	218	215	
number of deaths resulting from adverse events	9	15	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to bone			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	4 / 290 (1.38%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (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			
Malaise			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 290 (0.34%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fatigue			
subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Disease progression			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Death			
subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Chest pain			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sudden death			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pyrexia			
subjects affected / exposed	3 / 290 (1.03%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			

subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 290 (0.69%)	4 / 297 (1.35%)	
occurrences causally related to treatment / all	0 / 2	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cough			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Bronchial obstruction			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	4 / 290 (1.38%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hydrothorax			

subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumothorax			
subjects affected / exposed	2 / 290 (0.69%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 290 (0.69%)	4 / 297 (1.35%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 290 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive airways disorder			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
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	5 / 290 (1.72%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	6 / 7	0 / 3	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pneumonitis			

subjects affected / exposed	6 / 290 (2.07%)	13 / 297 (4.38%)	
occurrences causally related to treatment / all	6 / 7	14 / 16	
deaths causally related to treatment / all	1 / 1	2 / 2	
Respiratory failure			
subjects affected / exposed	2 / 290 (0.69%)	3 / 297 (1.01%)	
occurrences causally related to treatment / all	0 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Amylase increased			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition abnormal			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Neutrophil count decreased			

subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (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	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Palpitations			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Supraventricular tachycardia			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 290 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 290 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 290 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypotonia			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intrac			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			

subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (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			
Febrile neutropenia			
subjects affected / exposed	11 / 290 (3.79%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	11 / 11	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelosuppression			
subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	4 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			

subjects affected / exposed	0 / 290 (0.00%)	3 / 297 (1.01%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhegmatogenous retinal detachment			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			

subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 290 (0.00%)	5 / 297 (1.68%)	
occurrences causally related to treatment / all	0 / 0	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			

subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 290 (0.00%)	3 / 297 (1.01%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Pathological fracture			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			

subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	2 / 290 (0.69%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	2 / 290 (0.69%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	8 / 290 (2.76%)	5 / 297 (1.68%)	
occurrences causally related to treatment / all	2 / 9	0 / 6	
deaths causally related to treatment / all	0 / 1	0 / 1	
Bronchitis			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	3 / 290 (1.03%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	5 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			

subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 290 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 290 (0.69%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis infective			

subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 290 (0.34%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	23 / 290 (7.93%)	15 / 297 (5.05%)	
occurrences causally related to treatment / all	3 / 26	6 / 19	
deaths causally related to treatment / all	0 / 1	0 / 2	
Enterocolitis infectious			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	2 / 290 (0.69%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia serratia			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	2 / 290 (0.69%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Sepsis			
subjects affected / exposed	3 / 290 (1.03%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	1 / 2	
Septic shock			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 290 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 290 (0.34%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Docetaxel 75 mg/m^2	DS-1062a 6.0 mg/kg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	262 / 290 (90.34%)	273 / 297 (91.92%)	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 290 (2.76%)	15 / 297 (5.05%)	
occurrences (all)	14	27	
Alanine aminotransferase increased			
subjects affected / exposed	9 / 290 (3.10%)	16 / 297 (5.39%)	
occurrences (all)	12	30	
Blood creatinine increased			
subjects affected / exposed	4 / 290 (1.38%)	16 / 297 (5.39%)	
occurrences (all)	5	21	
Neutrophil count decreased			
subjects affected / exposed	41 / 290 (14.14%)	9 / 297 (3.03%)	
occurrences (all)	99	27	
Weight decreased			
subjects affected / exposed	13 / 290 (4.48%)	28 / 297 (9.43%)	
occurrences (all)	16	37	
White blood cell count decreased			
subjects affected / exposed	27 / 290 (9.31%)	6 / 297 (2.02%)	
occurrences (all)	60	15	
Nervous system disorders			
Peripheral sensory neuropathy			
subjects affected / exposed	15 / 290 (5.17%)	4 / 297 (1.35%)	
occurrences (all)	19	4	
Paraesthesia			
subjects affected / exposed	18 / 290 (6.21%)	4 / 297 (1.35%)	
occurrences (all)	20	4	
Neuropathy peripheral			
subjects affected / exposed	28 / 290 (9.66%)	4 / 297 (1.35%)	
occurrences (all)	45	4	
Headache			
subjects affected / exposed	14 / 290 (4.83%)	28 / 297 (9.43%)	
occurrences (all)	15	35	
Dysgeusia			

subjects affected / exposed	14 / 290 (4.83%)	17 / 297 (5.72%)	
occurrences (all)	17	18	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	72 / 290 (24.83%)	50 / 297 (16.84%)	
occurrences (all)	140	90	
Leukopenia			
subjects affected / exposed	20 / 290 (6.90%)	6 / 297 (2.02%)	
occurrences (all)	32	7	
Neutropenia			
subjects affected / exposed	40 / 290 (13.79%)	6 / 297 (2.02%)	
occurrences (all)	66	7	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	69 / 290 (23.79%)	70 / 297 (23.57%)	
occurrences (all)	107	139	
Chest pain			
subjects affected / exposed	12 / 290 (4.14%)	17 / 297 (5.72%)	
occurrences (all)	12	19	
Fatigue			
subjects affected / exposed	48 / 290 (16.55%)	48 / 297 (16.16%)	
occurrences (all)	70	59	
Malaise			
subjects affected / exposed	30 / 290 (10.34%)	21 / 297 (7.07%)	
occurrences (all)	45	34	
Oedema peripheral			
subjects affected / exposed	40 / 290 (13.79%)	13 / 297 (4.38%)	
occurrences (all)	56	15	
Pyrexia			
subjects affected / exposed	35 / 290 (12.07%)	22 / 297 (7.41%)	
occurrences (all)	49	25	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	17 / 290 (5.86%)	23 / 297 (7.74%)	
occurrences (all)	17	23	
Dry eye			

subjects affected / exposed	3 / 290 (1.03%)	21 / 297 (7.07%)	
occurrences (all)	3	23	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	65 / 290 (22.41%)	38 / 297 (12.79%)	
occurrences (all)	90	54	
Dry mouth			
subjects affected / exposed	9 / 290 (3.10%)	16 / 297 (5.39%)	
occurrences (all)	9	20	
Nausea			
subjects affected / exposed	54 / 290 (18.62%)	112 / 297 (37.71%)	
occurrences (all)	74	166	
Vomiting			
subjects affected / exposed	26 / 290 (8.97%)	47 / 297 (15.82%)	
occurrences (all)	37	65	
Constipation			
subjects affected / exposed	42 / 290 (14.48%)	58 / 297 (19.53%)	
occurrences (all)	47	70	
Stomatitis			
subjects affected / exposed	47 / 290 (16.21%)	148 / 297 (49.83%)	
occurrences (all)	65	279	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	46 / 290 (15.86%)	51 / 297 (17.17%)	
occurrences (all)	55	65	
Cough			
subjects affected / exposed	37 / 290 (12.76%)	45 / 297 (15.15%)	
occurrences (all)	46	56	
Oropharyngeal pain			
subjects affected / exposed	4 / 290 (1.38%)	16 / 297 (5.39%)	
occurrences (all)	4	18	
Haemoptysis			
subjects affected / exposed	15 / 290 (5.17%)	10 / 297 (3.37%)	
occurrences (all)	16	15	
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	14 / 290 (4.83%)	34 / 297 (11.45%)	
occurrences (all)	14	40	
Rash			
subjects affected / exposed	21 / 290 (7.24%)	40 / 297 (13.47%)	
occurrences (all)	26	45	
Alopecia			
subjects affected / exposed	101 / 290 (34.83%)	95 / 297 (31.99%)	
occurrences (all)	115	115	
Dry skin			
subjects affected / exposed	9 / 290 (3.10%)	21 / 297 (7.07%)	
occurrences (all)	10	21	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	10 / 290 (3.45%)	15 / 297 (5.05%)	
occurrences (all)	11	16	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	25 / 290 (8.62%)	6 / 297 (2.02%)	
occurrences (all)	33	7	
Back pain			
subjects affected / exposed	17 / 290 (5.86%)	19 / 297 (6.40%)	
occurrences (all)	21	23	
Arthralgia			
subjects affected / exposed	33 / 290 (11.38%)	27 / 297 (9.09%)	
occurrences (all)	46	36	
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	3 / 290 (1.03%)	15 / 297 (5.05%)	
occurrences (all)	3	19	
COVID-19			
subjects affected / exposed	23 / 290 (7.93%)	34 / 297 (11.45%)	
occurrences (all)	23	38	
Pneumonia			
subjects affected / exposed	12 / 290 (4.14%)	20 / 297 (6.73%)	
occurrences (all)	13	25	

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	63 / 290 (21.72%)	86 / 297 (28.96%)	
occurrences (all)	70	119	
Hypoalbuminaemia			
subjects affected / exposed	12 / 290 (4.14%)	17 / 297 (5.72%)	
occurrences (all)	13	25	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 October 2023	The main purpose of this amendment is to update the safety information for the DS-1062a investigational product.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

None reported

Notes: