Clinical trial results:
A Phase 4, Open-label, Single-Arm Study of Brentuximab Vedotin in Patients With Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma

Summary

EudraCT number	2012-004128-39
Trial protocol	GB CZ BE PT ES PL HU HR
Global end of trial date	29 August 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	C25006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01909934
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Ave, Lexington, MA, United States, 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main aim of this study was to determine the antitumor efficacy of single-agent brentuximab vedotin as measured by ORR in participants with relapsed or refractory sALCL following at least 1 multiagent chemotherapy regimen.

Protection of trial subjects:

Participant signed an informed consent form (ICF) before participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 January 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	10 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Croatia: 2
Country: Number of subjects enrolled	Czechia: 12
Country: Number of subjects enrolled	Hungary: 5
Country: Number of subjects enrolled	Poland: 8
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Romania: 3
Country: Number of subjects enrolled	Spain: 4
Country: Number of subjects enrolled	Türkiye: 6
Country: Number of subjects enrolled	United Kingdom: 6
Worldwide total number of subjects	50
EEA total number of subjects	38

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	33
From 65 to 84 years	16
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 23 January 2014 to 29 August 2024.

Pre-assignment

Screening details:

Participants with a diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma were enrolled to receive brentuximab vedotin 1.8 milligrams per kilogram (mg/kg).

Period 1

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

Arms

Arm title	Brentuximab Vedotin 1.8 mg/kg

Arm description:

Participants received brentuximab vedotin 1.8 mg/kg as a 30 minute intravenous (IV) infusion on Day 1 of each 3 week cycle. Participants with stable disease or better and without unacceptable toxicity were to receive a minimum of 8 cycles with the opportunity to receive a maximum of 16 cycles.

Arm type	Experimental
Investigational medicinal product name	ADCETRIS
Investigational medicinal product code	SGN-35
Other name	BRENTUXIMAB VEDOTIN
Pharmaceutical forms	Powder for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Brentuximab vedotin 1.8 mg/kg on Day 1 of each 3-week cycle.

Number of subjects in period 1	Brentuximab Vedotin 1.8 mg/kg
Started	50
Completed	19
Not completed	31
Adverse event, serious fatal	25
Consent withdrawn by subject	3
Reason Not Specified	1
Lost to follow-up	1
Withdrawal of Informed Consent	1

Baseline characteristics

Reporting groups	
Reporting group title	Brentuximab Vedotin 1.8 mg/kg
Reporting group description:	
Participants received brentuximab vedotin 1.8 mg/kg as a 30 minute intravenous (IV) infusion on Day 1 of each 3 week cycle. Participants with stable disease or better and without unacceptable toxicity were to receive a minimum of 8 cycles with the opportunity to receive a maximum of 16 cycles.	

Reporting group values	Brentuximab Vedotin 1.8 mg/kg	Total	
Number of subjects	50	50	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	56.4		
standard deviation	± 16.70	-	
Gender categorical Units: Subjects			
Male	19	19	
Female	31	31	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	50	50	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethinicity Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	45	45	
Unknown or Not Reported	3	3	
Height Units: centimeters (cm)			
arithmetic mean	166.8		
standard deviation	± 10.40	-	
Weight Units: kilograms (kg)			
arithmetic mean	75.2		
standard deviation	± 20.73	-	
Body Mass Index (BMI) Units: kilograms per meter squared (kg/m^2)			
arithmetic mean	26.9		

standard deviation	± 6.39	-	

End points

End points reporting groups

Reporting group title	Brentuximab Vedotin 1.8 mg/kg

Reporting group description:

Participants received brentuximab vedotin 1.8 mg/kg as a 30 minute intravenous (IV) infusion on Day 1 of each 3 week cycle. Participants with stable disease or better and without unacceptable toxicity were to receive a minimum of 8 cycles with the opportunity to receive a maximum of 16 cycles.

Primary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)[1]

End point description:

ORR was defined as the percentage of participants with a complete remission (CR) or partial remission (PR) by Independent Review Facility (IRF) response assessment according to the International Working Group (IWG) Revised Response Criteria for Malignant Lymphoma. CR is defined as the disappearance of all evidence of disease and PR is defined as regression of measurable disease and no new sites. Intent-to-Treat Population included all participants enrolled in the study.

End point type	Primary

End point timeframe:

Up to data cut-off date: 04 May 2021 (Up to approximately 7 years)

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: Only descriptive analysis was planned for this endpoint.

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percentage of participants				
number (confidence interval 95%)	64 (49 to 77)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) as Per IRF

End point title	Progression-free Survival (PFS) as Per IRF

End point description:

PFS is defined as the time from start of study treatment to first documentation of objective tumor progression or to death due to any cause, whichever comes first. PFS per IRF is based upon the radiological assessment from an independent review facility. Intent-to-Treat Population included all participants enrolled in the study. '99999' indicates that upper limit of 95% CI was not estimable due to insufficient number of participants with events up to data cut-off date: 4 May 2021.

End point type	Secondary

End point timeframe:

Until disease progression, death, or the data cut-off date: 4 May 2021 (Up to approximately 7 years)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: months				
median (confidence interval 95%)	20.9 (4.17 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Treatment-emergent Adverse Events (TEAEs), Serious TEAEs, Related TEAEs and TEAEs by Severity (Grade 3 or Higher)

End point title	Percentage of Participants With Treatment-emergent Adverse Events (TEAEs), Serious TEAEs, Related TEAEs and TEAEs by Severity (Grade 3 or Higher)

End point description:

An adverse event (AE): any untoward medical occurrence in a participant administered a pharmaceutical product; the untoward medical occurrence does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product whether or not it is related to medicinal product. TEAE was defined as any AE that started after the first administration of study drug in this continuation study. Serious TEAEs: defined as any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of an existing hospitalization, results in persistent or significant disability or incapacity, is a congenital anomaly/birth defect, or is a medically important event. Safety population: all participants who received at least 1 dose of brentuximab vedotin.

End point type	Secondary

End point timeframe:

From first dose up to 30 days post last dose of study drug (Up to approximately 1 year)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percentage of participants				
number (not applicable)				
TEAEs	94			
Serious TEAEs	32			
Drug-Related TEAEs	70			
TEAEs by Severity (Grade 3 or Higher)	58			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Receiving Hematopoietic Stem Cell Transplant (SCT) Following Treatment With Brentuximab Vedotin

End point title	Percentage of Participants Receiving Hematopoietic Stem Cell Transplant (SCT) Following Treatment With Brentuximab Vedotin

End point description:

Intent-to-Treat Population included all participants enrolled in the study.

End point type	Secondary

End point timeframe:

Until disease progression, death, or end of study (Up to approximately 10.7 years)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percentage of participants				
number (not applicable)	28			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Per IRF

End point title	Duration of Response (DOR) as Per IRF

End point description:

DOR was defined as the time between initial response and documented tumor progression in the subset of participants who achieved an objective response, either CR or PR. DOR per IRF was based upon the radiological assessment of measured lesions from an independent review facility. DOR was censored on the date of the last disease assessment documenting absence of progressive disease (PD) for participants who were lost to follow-up, withdrew consent, started a new anticancer therapy other than stem cell transplant (SCT), or discontinued treatment due to undocumented PD after the last adequate disease assessment. '999' indicates that median and upper limit of confidence interval (CI) were not estimable as most of the responders were censored. Intent-to-Treat Population included all participants enrolled in the study. Only responders were analyzed for this outcome measure.

End point type	Secondary

End point timeframe:

Until disease progression, death, or the data cut-off date: 4 May 2021 (Up to approximately 7 years)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: months				
median (confidence interval 95%)	999 (19.71 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS is defined as the time from start of study treatment to date of death due to any cause. Intent-to-Treat Population included all participants enrolled in the study. '99999' denotes that upper limit of 95% CI was not estimable due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

Until disease progression, death, or end of study (Up to approximately 10.7 years)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: months				
number (confidence interval 95%)	67.6 (17.68 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Concentration for Unconjugated Drug- Monomethyl Auristatin E (MMAE)

End point title	Maximum Concentration for Unconjugated Drug- Monomethyl Auristatin E (MMAE)

End point description:

Pharmacokinetic population included participants who received at least 1 dose of brentuximab vedotin and have PK concentration data available. 'n' denotes number of participants with data available for analyses at the given timepoint.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 and Cycle 3, Day 1 at the end of infusion

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: nanogram per milliliter (ng/ml)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1 (n=49) Cycle 3, Day 1 (n=38)	0.25 (± 87) 0.29 (± 88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Remission Rate (CRR) as Per IRF

End point title	Complete Remission Rate (CRR) as Per IRF

End point description:

CRR is defined as percentage of participants with CR. CR is defined as the disappearance of all evidence of disease. Intent-to-Treat Population included all participants enrolled in the study.

End point type	Secondary

End point timeframe:

Until disease progression, death, or the data cut-off date: 4 May 2021 (Up to approximately 7 years)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: percentage of participants				
number (confidence interval 95%)	30 (18 to 45)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of Serum Antibody-drug Conjugate (ADC) at the End of Infusion

End point title	Concentration of Serum Antibody-drug Conjugate (ADC) at the End of Infusion

End point description:

Pharmacokinetic population included participants who received at least 1 dose of brentuximab vedotin and have PK concentration data available. 'n' denotes number of participants with data available for

analyses at the given timepoint.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 and Cycle 3, Day 1 at the end of infusion

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: micrograms per liter (µg/L)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1 (n=48)	35 (± 35)			
Cycle 3, Day 1 (n=38)	38 (± 25)			

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of Serum Total Antibody (TAb) Conjugate Plus Free Total Antibody

End point title	Concentration of Serum Total Antibody (TAb) Conjugate Plus Free Total Antibody

End point description:

Pharmacokinetic population included participants who received at least 1 dose of brentuximab vedotin and have PK concentration data available. 'n' denotes number of participants with data available for analyses at the given timepoint.

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 and Cycle 3, Day 1 at the end of infusion

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: µg/L				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1 (n=48)	33 (± 29)			
Cycle 3, Day 1 (n=36)	38 (± 23)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Presence of Anti-Therapeutic Antibodies (ATA) and Neutralizing Antidrug Antibody (Nab) to Brentuximab Vedotin

End point title	Percentage of Participants With Presence of Anti-Therapeutic Antibodies (ATA) and Neutralizing Antidrug Antibody (Nab) to Brentuximab Vedotin

End point description:

Immunogenicity evaluable population included all participants who received at least 1 dose of brentuximab vedotin and had a baseline and at least 1 post-baseline sample available for evaluation for the presence of ATA and Nab. Subjects analysed are participants with data available for analyses at the given timepoint.

End point type	Secondary

End point timeframe:

Up to 16 cycles (each cycle = 21 days)

End point values	Brentuximab Vedotin 1.8 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: percentage of participants				
number (not applicable)				
ATA Positive	30			
Neutralizing ATA Positive	0.0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Throughout the study (Up to approximately 10.7 years); Serious and other adverse events: From first dose up to 30 days post last dose of study drug (up to approximately 1 year)

Adverse event reporting additional description:

The Safety Population included all participants who received at least 1 dose of brentuximab vedotin.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Brentuximab Vedotin 1.8 mg/kg

Reporting group description:

Participants received brentuximab vedotin 1.8 mg/kg as a 30 minute IV infusion on Day 1 of each 3 week cycle. Participants with stable disease or better and without unacceptable toxicity were to receive a minimum of 8 cycles with the opportunity to receive a maximum of 16 cycles.

Serious adverse events	Brentuximab Vedotin 1.8 mg/kg		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 50 (32.00%)		
number of deaths (all causes)	25		
number of deaths resulting from adverse events	5		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anaplastic large cell lymphoma T- and null-cell types			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Invasive lobular breast carcinoma			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			

subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure acute			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Autonomic neuropathy			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Central nervous system haemorrhage			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ischaemic stroke			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Death			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Neutropenia			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestinal haemorrhage			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Respiratory failure				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Pneumonitis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	1 / 1			
Dyspnoea				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Epididymitis				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Malnutrition				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Hypokalaemia			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Decreased appetite			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Brentuximab Vedotin 1.8 mg/kg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 50 (74.00%)		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	7		
Paraesthesia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	7		
Peripheral motor neuropathy			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	5		
Peripheral sensory neuropathy			
subjects affected / exposed	9 / 50 (18.00%)		
occurrences (all)	13		
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	5		

Anaemia			
subjects affected / exposed	7 / 50 (14.00%)		
occurrences (all)	10		
Neutropenia			
subjects affected / exposed	8 / 50 (16.00%)		
occurrences (all)	14		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	9 / 50 (18.00%)		
occurrences (all)	15		
Oedema peripheral			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Malaise			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	6 / 50 (12.00%)		
occurrences (all)	6		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Nausea			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
Diarrhoea			
subjects affected / exposed	8 / 50 (16.00%)		
occurrences (all)	8		
Vomiting			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	6		
Back pain			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Myalgia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Pain in extremity			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	6		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
Hyponatraemia			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 March 2013	The following updates were made as per protocol amendment 01: 1. Specified that a minimum of 45 participants were to be treated in this study. 2. Increased the duration of disease status follow-up. 3. Added a criterion excluding participants who had received any investigational products within 4 weeks before the first dose of brentuximab vedotin.
27 August 2021	The following update was made as per protocol amendment 02: 1. Updated the sponsor's name and legal entity responsible for the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported