Clinical trial results:
Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of BNT411 as a monotherapy in subjects with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC)

Summary

EudraCT number	2019-003593-17
Trial protocol	DE ES GB
Global end of trial date	23 May 2024
Results information	
Result version number	v1 (current)
This version publication date	09 May 2025
First version publication date	09 May 2025

Trial information

Trial identification	
Sponsor protocol code	BNT411-01
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04101357
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube, 12 , Mainz, Germany, 55131
Public contact	Clinical Trials Information, BioNTech SE, 0049 6131 – 9084 – 7691, patients@biontech.de
Scientific contact	Clinical Trials Information, BioNTech SE, 0049 6131 – 9084 – 7691, patients@biontech.de

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	01 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 May 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the safety profile and determine the maximum tolerated dose (MTD) and/or recommended phase 2 dose (RP2D) of BNT411 in a mixed population of subjects with solid tumors.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 June 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	Spain: 16
Country: Number of subjects enrolled	United Kingdom: 15
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	54
EEA total number of subjects	22

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)	39
From 65 to 84 years	15

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The trial was planned with three parts: Part 1A, Part 1B, and Part 2. Part 2, which was planned to consist of expansion cohorts in solid tumors, was not conducted as the trial was terminated prematurely.

Pre-assignment

Screening details:

A total of 54 subjects were enrolled in the study, out of which 52 subjects received the treatment with the study drug. Two subjects were enrolled but not treated, hence not included in the started count.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg

Arm description:

Subjects received BNT411 at a starting dose of 0.05 microgram/kilogram (mcg/kg) as an intravenous (IV) infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable adverse events (AEs), withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 0.15 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 0.45 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks

(on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 4.8 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 6.0 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 7.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT-411
Investigational medicinal product code	BNT-411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 9.6 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

BNT411 was administered as IV infusion.

Arm title	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details: BNT411 was administered as IV infusion.	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Atezolizumab 1200 mg was administered by IV infusion.	
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Carboplatin was administered by IV infusion.	
Investigational medicinal product name	Etoposide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Etoposide 100 mg/m^2 was administered by IV infusion.	
Arm title	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg

Arm description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Arm type	Experimental
Investigational medicinal product name	BNT411
Investigational medicinal product code	BNT411
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: BNT411 was administered as IV infusion.	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Atezolizumab 1200 mg was administered by IV infusion.	
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Carboplatin was administered by IV infusion.	

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

Dosage and administration details:

Etoposide 100 mg/m^2 was administered by IV infusion.

Number of subjects in period 1[1]	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg
Started	2	1	1
Treated	2	1	1
Completed	0	0	0
Not completed	2	1	1
Consent withdrawn by subject	1	-	-
Trial closure	-	-	-
Death	1	1	1
Unspecified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg
Started	3	4	14
Treated	3	4	14
Completed	0	0	0
Not completed	3	4	14
Consent withdrawn by subject	-	-	-
Trial closure	-	-	2
Death	2	4	11
Unspecified	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1[1]	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg
Started	8	6	6
Treated	8	6	6
Completed	0	0	0
Not completed	8	6	6
Consent withdrawn by subject	-	-	1
Trial closure	2	-	-
Death	4	4	5

Unspecified	2	1	-
Lost to follow-up	-	1	-

Number of subjects in period 1[1]	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg
Started	3	4
Treated	3	4
Completed	0	0
Not completed	3	4
Consent withdrawn by subject	1	-
Trial closure	-	1
Death	2	3
Unspecified	-	-
Lost to follow-up	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 52 subjects received the treatment with the study drug. Two subjects were enrolled but not treated.

Reporting groups

Reporting group title	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg

Reporting group description:

Subjects received BNT411 at a starting dose of 0.05 microgram/kilogram (mcg/kg) as an intravenous (IV) infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable adverse events (AEs), withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.15 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.45 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 4.8 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 6.0 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 7.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 9.6 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg
Number of subjects	2	1	1
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	1	1	1
>=65 years	1	0	0
Gender categorical Units: Subjects			
Female	1	1	0
Male	1	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	1	1	1
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	2	1	1
Asian	0	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reportable	0	0	0
Other	0	0	0
Unknown	0	0	0

Reporting group values	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg
Number of subjects	3	4	14
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	1	11

>=65 years	0	3	3

Gender categorical Units: Subjects			
Female	0	2	6
Male	3	2	8
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	4	14
Unknown or Not Reported	0	0	0
Race Units: Subjects			
White	2	3	11
Asian	0	1	0
Black or African American	0	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reportable	0	0	0
Other	0	0	0
Unknown	1	0	2

Reporting group values	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg
Number of subjects	8	6	6
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	6	5	4
>=65 years	2	1	2
Gender categorical Units: Subjects			
Female	3	2	5
Male	5	4	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	8	5	5
Unknown or Not Reported	0	1	0
Race Units: Subjects			
White	8	5	5
Asian	0	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reportable	0	0	0
Other	0	0	0
Unknown	0	1	1

Reporting group values	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	Total
Number of subjects	3	4	52
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	1	3	37
>=65 years	2	1	15
Gender categorical Units: Subjects			
Female	1	3	24
Male	2	1	28
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	3	4	49
Unknown or Not Reported	0	0	1
Race Units: Subjects			
White	3	4	45
Asian	0	0	1
Black or African American	0	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Not Reportable	0	0	0
Other	0	0	0
Unknown	0	0	5

End points

End points reporting groups

Reporting group title	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg

Reporting group description:

Subjects received BNT411 at a starting dose of 0.05 microgram/kilogram (mcg/kg) as an intravenous (IV) infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable adverse events (AEs), withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.15 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.45 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 4.8 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 6.0 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 7.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 9.6 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Subject analysis set title	All Subjects
Subject analysis set type	Safety analysis

Subject analysis set description:

All Subjects in Part 1A and B who received IV infusions of BNT411 every week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15 in Part 1A; on Days 2, 8, and 15 in Part 1B; cycle duration=21 days). Thereafter, BNT411 was administered every 3 weeks (on Day 1 [Part 1A] or Day 2 [Part 1B] of each 3-week cycle) until progressive disease, unacceptable AEs, withdrawal of consent, lost to follow-up or death whichever occurs first.

Primary: Number of Subjects With Dose Limiting Toxicities (DLTs)

End point title	Number of Subjects With Dose Limiting Toxicities (DLTs)[1]

End point description:

DLTs were defined as any non-immune-related adverse events (AEs) or immune-related AEs during the first treatment cycle that was of Grade 3 and that did not resolve to Grade 1 or lower within a week, or that were of Grade 4. AEs were graded for severity using National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0 (NCI-CTCAE v5.0), where Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4 - Life-threatening consequences; and Grade 5: Death related to AE. Analysis was performed on DLT evaluable set that included subjects who received at least one dose of BNT411 and have completed the DLT evaluation period and meet the minimum exposure criterion or have experienced a DLT during the DLT evaluation period (Cycle 1).

End point type	Primary

End point timeframe:

Cycle 1 (21 Days)

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: As the primary endpoint was descriptive in nature, no formal statistical analysis was planned.

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: Subjects	0	0	0	0

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	6	6
Units: Subjects	0	0	0	2

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	2	3	
Units: Subjects	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs (TESAEs) and Grade >=3 TEAEs

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs (TESAEs) and Grade >=3 TEAEs[2]

End point description:

TEAE was defined as any AE with an onset date on or after the first administration of trial treatment (if AE was absent before the first administration of trial treatment) or worsened after the first administration of trial treatment (if AE was present before the first administration of trial treatment). AEs occurring more than 60 days after last treatment administration were considered as treatment-emergent only if assessed as related to the trial treatment by the investigator. Serious adverse event (SAE): any untoward medical occurrence that, at any dose: resulted in death; was life-threatening; required inpatient hospitalisation or prolongation of existing hospitalisation; resulted in persistent disability/incapacity; was a congenital anomaly/birth defect or was another medically important condition. AE were graded for severity using NCI-CTCAE v5.0, where Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4 - Life-threatening consequences; and Grade 5: Death related.

End point type	Primary

End point timeframe:

From Baseline until 60 days after last dose of study treatment (3 years and 11 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: As the primary endpoint was descriptive in nature, no formal statistical analysis was planned.

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: subjects				
TEAE	2	1	1	3
Related TEAE	2	1	0	2
Grade >=3 TEAE	1	0	1	0

Related Grade >=3 TEAE	0	0	0	0
TESAE	1	0	1	0
Related TESAE	0	0	0	0
TESAE leading to Death	1	0	1	0
Related TESAE leading to Death	0	0	0	0

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: subjects				
TEAE	4	14	8	6
Related TEAE	1	13	7	6
Grade >=3 TEAE	3	3	3	5
Related Grade >=3 TEAE	0	2	2	3
TESAE	1	5	3	4
Related TESAE	0	3	1	3
TESAE leading to Death	0	0	1	0
Related TESAE leading to Death	0	0	0	0

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: subjects				
TEAE	6	3	4	
Related TEAE	6	3	4	
Grade >=3 TEAE	5	3	3	
Related Grade >=3 TEAE	5	3	3	
TESAE	3	2	3	
Related TESAE	3	2	2	
TESAE leading to Death	0	1	0	
Related TESAE leading to Death	0	1	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects Reporting Dose Reduction and/or Discontinuation of BNT411 Due to TEAEs

End point title	Number of Subjects Reporting Dose Reduction and/or Discontinuation of BNT411 Due to TEAEs[3]

End point description:

Subjects with dose reduction and/or discontinuation of BNT411 due to TEAEs are reported. Analysis was performed on safety set defined as all subjects who received at least one dose of BNT411.

End point type	Primary

End point timeframe:

From Baseline until 60 days after last dose of study treatment (3 years and 11 months)

Notes:

[3] - 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: As the primary endpoint was descriptive in nature, no formal statistical analysis was planned.

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: Subjects				
Dose Reduction of BNT411	0	0	0	0
Discontinuation of BNT411 due to TEAEs	1	0	1	0

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: Subjects				
Dose Reduction of BNT411	0	1	1	3
Discontinuation of BNT411 due to TEAEs	0	1	1	1

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: Subjects				
Dose Reduction of BNT411	3	0	0	
Discontinuation of BNT411 due to TEAEs	0	1	3	

Statistical analyses

No statistical analyses for this end point

Primary: Maximal Tolerated Dose (MTD) of BNT411

End point title	Maximal Tolerated Dose (MTD) of BNT411[4]

End point description:

The MTD defined as the highest tolerated dose was reported based on the DLTs and TEAEs experienced by subjects. Analysis was performed on DLT evaluable set. Data for this endpoint was planned to be analysed and reported for all subjects collectively.

End point type	Primary

End point timeframe:

Cycle 1 (21 days)

Notes:

[4] - 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: As the primary endpoint was descriptive in nature, no formal statistical analysis was planned.

End point values	All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: microgram/kilogram (mcg/kg)				
number (not applicable)	6.0			

Statistical analyses

No statistical analyses for this end point

Primary: Recommended Phase 2 Dose (RP2D) of BNT411

End point title	Recommended Phase 2 Dose (RP2D) of BNT411[5]

End point description:

RP2D was based on integrated evaluation of safety, tolerability, clinical benefit, pharmacokinetic (PK), and pharmacodynamic data, for all dose levels was tested. Analysis was performed on DLT evaluable population. Data for this endpoint was planned to be analysed and reported for all subjects collectively.

End point type	Primary

End point timeframe:

Cycle 1 (21 days)

Notes:

[5] - 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: As the primary endpoint was descriptive in nature, no formal statistical analysis was planned.

End point values	All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: microgram/kilogram (mcg/kg)				
number (not applicable)	4.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK) Assessment for BNT411: Area Under the Concentration Time Curve (AUC0-last)

End point title	Pharmacokinetics (PK) Assessment for BNT411: Area Under the Concentration Time Curve (AUC0-last)

End point description:

AUC0-last defined as the AUC from time 0 to the last measurable time-point was calculated from plasma concentrations of BNT411 using the linear-log trapezoidal method. Analysis was performed on PK evaluable set that included all subjects who received at least one dose of BNT411 and have at least one quantifiable post dose PK sample. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit, and "99999" in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: (h)*picogram (pg)/milliliters (mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	187.3477 (± 99999)	1477.6656 (± 99999)	3123.7583 (± 99999)	4724.5276 (± 3433.94480)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	327.1261 (± 143.16329)	3341.8368 (± 99999)	2313.8369 (± 99999)	4635.3150 (± 3330.49325)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6

Units: (h)*picogram (pg)/milliliters (mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	9445.2536 (± 3902.75812)	18735.9783 (± 11750.72661)	22365.2916 (± 8763.37410)	49384.9308 (± 31393.75269)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	11745.1614 (± 2871.09499)	20998.2267 (± 11223.40206)	18392.6594 (± 7546.26734)	26266.1125 (± 18091.16303)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: (h)*picogram (pg)/milliliters (mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	29680.3554 (± 12850.18934)	999 (± 9999)	999 (± 9999)	
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	28693.3094 (± 7377.64393)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	3604.2235 (± 1804.20847)	6258.0743 (± 1565.55574)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	3543.6926 (± 4508.63205)	3369.5271 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Clearance (CL)

End point title	PK Assessment for BNT411: Clearance (CL)

End point description:

Clearance reflects the elimination of the drug from the body was estimated from plasma concentrations of BNT411 as Dose/AUC0-inf. Dose was converted, as necessary, to reflect the amount of anhydrous BNT411 administered. Analysis was performed on PK evaluable set. Here, “number of subjects analysed” = subjects with available data for this endpoint and “n” signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and “99999” in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: liters (L)/hours(h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	27.6502 (± 99999)	8.3063 (± 99999)	13.1362 (± 99999)	36.6351 (± 34.63090)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	999 (± 9999)	3.5213 (± 99999)	17.6849 (± 99999)	28.0090 (± 14.49788)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: liters (L)/hours(h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	21.1677 (± 8.41500)	23.6285 (± 9.44317)	24.7574 (± 24.89704)	13.4479 (± 6.36326)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	13.9638 (± 2.28039)	22.2684 (± 13.53332)	25.7574 (± 14.62545)	20.8883 (± 3.90723)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: liters (L)/hours(h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	24.4680 (± 9.09568)	999 (± 9999)	999 (± 9999)	
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	21.9203 (± 10.72759)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	20.5762 (± 10.33093)	30.8326 (± 5.92557)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	14.3209 (± 99999)	38.3186 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Volume of Distribution (Vd)

End point title	PK Assessment for BNT411: Volume of Distribution (Vd)

End point description:

Volume of distribution (Vd) is defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired plasma concentration of a drug. Vd was estimated from plasma concentrations of BNT411. Analysis was performed on PK evaluable set. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and "99999" in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: Liters (L)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	75.5414 (± 99999)	47.0697 (± 99999)	108.1691 (± 99999)	296.6890 (± 313.18628)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	999 (± 9999)	18.6963 (± 99999)	159.4620 (± 99999)	194.0698 (± 97.37669)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: Liters (L)				

arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	220.7140 (± 74.05373)	232.0475 (± 100.19550)	168.7668 (± 145.45978)	156.7781 (± 77.21878)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	127.2646 (± 21.21154)	187.7812 (± 96.09022)	163.0226 (± 44.35908)	186.4341 (± 31.41644)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: Liters (L)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	222.3040 (± 85.88236)	999 (± 9999)	999 (± 9999)	
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	148.4863 (± 125.70109)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	132.8456 (± 22.90794)	205.7365 (± 14.86844)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	125.7815 (± 99999)	243.8492 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Maximum Plasma Concentration (Cmax)

End point title	PK Assessment for BNT411: Maximum Plasma Concentration (Cmax)

End point description:

Cmax defined as the maximum observed plasma concentration was estimated from plasma concentrations of BNT411. Analysis was performed on the PK evaluable set. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and "99999" in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	152.0 (± 99999)	1020.0 (± 99999)	2437.0 (± 99999)	3229.3 (± 1847.84)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	254.0 (± 57.98)	2163.0 (± 99999)	1520.0 (± 99999)	2947.3 (± 1281.14)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	8191.3 (± 3211.56)	13005.9 (± 4681.33)	20404.6 (± 8137.20)	31596.8 (± 10260.05)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	8104.7 (± 1473.43)	14804.4 (± 6042.78)	13800.0 (± 3642.80)	19551.8 (± 16904.30)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	25967.7 (± 10270.43)	999 (± 9999)	999 (± 9999)	
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	22547.8 (± 7933.89)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (± 9999)	2880.33 (± 2065.462)	5598.25 (± 766.713)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (± 9999)	2993.95 (± 4214.427)	2900.00 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Time to Reach Cmax (Tmax)

End point title	PK Assessment for BNT411: Time to Reach Cmax (Tmax)

End point description:

Tmax defined as the time to reach maximum (peak) concentration was estimated from plasma concentrations of BNT411. Analysis population includes the PK evaluable set. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data at respective visit. Here, "-999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and "-9999 to 99999" in the data analysis field signifies that full range could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: hours (h)				
median (full range (min-max))				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	0.7667 (-9999 to 99999)	0.5000 (0.500 to 0.500)	0.5667 (-9999 to 99999)	0.6500 (0.533 to 0.683)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	0.5750 (0.567 to 0.583)	0.5000 (0.500 to 0.500)	0.5833 (-9999 to 99999)	0.5833 (0.583 to 0.700)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: hours (h)				

median (full range (min-max))				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	0.5417 (0.500 to 0.600)	0.5917 (0.500 to 0.867)	0.6000 (0.550 to 0.700)	0.5417 (0.500 to 0.717)
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	0.5000 (0.500 to 0.583)	0.6000 (0.500 to 0.817)	0.6167 (0.583 to 0.617)	0.6333 (0.567 to 0.667)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)	999 (-999 to 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: hours (h)				
median (full range (min-max))				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,6,6,0,0)	0.6000 (0.500 to 0.667)	999 (-999 to 9999)	999 (-999 to 9999)	
Cycle 2 Day 1 (n=2,1,1,3,3,10,3,4,4,0,0)	0.6417 (0.600 to 0.750)	999 (-999 to 9999)	999 (-999 to 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,3,4)	999 (-999 to 9999)	0.5833 (0.500 to 1.017)	0.6000 (0.500 to 0.850)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,2,1)	999 (-999 to 9999)	13.1083 (0.633 to 25.583)	0.5833 (-9999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Trough Concentration (Ctrough)

End point title	PK Assessment for BNT411: Trough Concentration (Ctrough)

End point description:

Ctrough defined as the pre-dose concentrations of BNT411 was estimated from the plasma concentrations of BNT411. Analysis was performed on PK evaluable set. Here, “number of subjects analysed” = subjects with available data for this endpoint and “n” signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and “99999” in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis

End point type	Secondary

End point timeframe:

Part 1A: Start of infusion on Cycle 1 Day 8, Day 15, Day 22, Day 43; Day 85; Part 1B: Start of infusion on Cycle 1 Day 8, Day 15, Day 23, Day 44 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 8 (n=1,1,1,2,1,8,6,2,4,2,1)	0.000 (± 99999)	0.000 (± 99999)	0.000 (± 99999)	0.000 (± 0.0000)
Cycle 1 Day 15 (n= 2,0,1,3,4,6,4,2,2,1,4)	8.400 (± 11.8794)	999 (± 9999)	0.000 (± 99999)	0.000 (± 0.0000)
Cycle 1 Day 22 (n=2,0,1,2,2,8,2,1,1,0,0)	0.000 (± 0.0000)	999 (± 9999)	0.000 (± 99999)	51.500 (± 72.8320)
Cycle 1 Day 23 (n=0,0,0,0,0,0,0,0,0,0,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 1 Day 43 (n=1,0,0,3,1,3,1,2,1,0,0)	0.000 (± 99999)	999 (± 9999)	999 (± 9999)	4.833 (± 8.3716)
Cycle 1 Day 44 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 1 Day 85 (n=0,0,0,2,0,0,1,1,1,0,0)	999 (± 9999)	999 (± 9999)	999 (± 9999)	0.590 (± 0.8344)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 8 (n=1,1,1,2,1,8,6,2,4,2,1)	0.000 (± 99999)	0.476 (± 0.9789)	0.000 (± 0.0000)	0.000 (± 0.0000)
Cycle 1 Day 15 (n= 2,0,1,3,4,6,4,2,2,1,4)	0.253 (± 0.5050)	0.168 (± 0.4123)	0.580 (± 0.6722)	1.350 (± 0.2970)
Cycle 1 Day 22 (n=2,0,1,2,2,8,2,1,1,0,0)	0.000 (± 0.0000)	0.000 (± 0.0000)	0.000 (± 0.0000)	1.770 (± 99999)
Cycle 1 Day 23 (n=0,0,0,0,0,0,0,0,0,0,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 1 Day 43 (n=1,0,0,3,1,3,1,2,1,0,0)	0.000 (± 99999)	0.370 (± 0.6409)	0.000 (± 99999)	0.970 (± 1.3718)
Cycle 1 Day 44 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 1 Day 85 (n=0,0,0,2,0,0,1,1,1,0,0)	999 (± 9999)	999 (± 9999)	38500.000 (± 99999)	1.170 (± 99999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: picogram/ milliliters (pg/mL)				
arithmetic mean (standard deviation)				
Cycle 1 Day 8 (n=1,1,1,2,1,8,6,2,4,2,1)	0.000 (± 0.0000)	0.0 (± 0.00)	0.0 (± 99999)	
Cycle 1 Day 15 (n= 2,0,1,3,4,6,4,2,2,1,4)	1.655 (± 0.5303)	0.0 (± 99999)	0.0 (± 0.00)	
Cycle 1 Day 22 (n=2,0,1,2,2,8,2,1,1,0,0)	0.000 (± 99999)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 23 (n=0,0,0,0,0,0,0,0,0,0,1)	999 (± 9999)	999 (± 9999)	0.0 (± 99999)	
Cycle 1 Day 43 (n=1,0,0,3,1,3,1,2,1,0,0)	1.690 (± 99999)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 44 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	0.0 (± 99999)	0.0 (± 99999)	
Cycle 1 Day 85 (n=0,0,0,2,0,0,1,1,1,0,0)	0.000 (± 99999)	999 (± 9999)	999 (± 9999)	

Statistical analyses

No statistical analyses for this end point

Secondary: PK Assessment for BNT411: Terminal Elimination Half-life (T1/2)

End point title	PK Assessment for BNT411: Terminal Elimination Half-life (T1/2)

End point description:

Terminal elimination half-life was estimated from the plasma concentrations of BNT411. Analysis was performed on PK evaluable set. Here, “number of subjects analysed” = subjects with available data for this endpoint and “n” signifies subjects with available data at respective visit. Here, "999 and 9999" are used as placeholders in the data field which signifies that no subjects were available for analysis at the specified visit and “99999” in the data analysis field signifies that standard deviation could not be calculated as only 1 subject was available for the analysis.

End point type	Secondary

End point timeframe:

Part 1A: Cycle 1 Day 1; Cycle 2 Day 1; Part 1B: Cycle 1 Day 2; Cycle 2 Day 2 (each cycle duration=21 days)

End point values	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	1	3
Units: hours (h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	1.8937 (± 99999)	3.9279 (± 99999)	5.7077 (± 99999)	5.2525 (± 0.99582)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	999 (± 9999)	3.6803 (± 99999)	6.2500 (± 99999)	4.9020 (± 0.57744)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	14	8	6
Units: hours (h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	7.4679 (± 1.87347)	7.4600 (± 4.30673)	5.1189 (± 1.23014)	8.7346 (± 4.71577)
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	6.3386 (± 0.73577)	6.0603 (± 1.18916)	4.9479 (± 1.51079)	6.2166 (± 0.45957)
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	999 (± 9999)	999 (± 9999)	999 (± 9999)

End point values	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	3	4	
Units: hours (h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1 (n=1,1,1,3,4,14,7,5,6,0,0)	6.2721 (± 0.48131)	999 (± 9999)	999 (± 9999)	
Cycle 2 Day 1 (n=0,1,1,3,3,10,3,3,4,0,0)	4.5667 (± 2.07892)	999 (± 9999)	999 (± 9999)	
Cycle 1 Day 2 (n=0,0,0,0,0,0,0,0,0,2,4)	999 (± 9999)	4.8989 (± 1.68795)	4.7244 (± 0.68988)	
Cycle 2 Day 2 (n=0,0,0,0,0,0,0,0,0,1,1)	999 (± 9999)	6.0880 (± 99999)	4.4110 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From Baseline until 60 days after last dose of study treatment (3 years and 11 months)

Adverse event reporting additional description:

All-cause mortality analysis was performed on all enrolled subjects. All SAEs and Non-Serious AEs data collected throughout the study are reported in the AE section and analysis was performed on safety analysis set (that is, all subjects who received at least one dose of BNT411).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg

Reporting group description:

Subjects received BNT411 at a starting dose of 0.05 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AEs, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.15 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 0.45 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 2.4 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 6.0 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost

to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 7.2 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 9.6 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 1.2 mcg/kg as an IV infusion in combination with atezolizumab, carboplatin and etoposide once a week in a 3-week cycle for the first 4 cycles (on Days 2, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 2) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Reporting group title	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg

Reporting group description:

Subjects received BNT411 at a dose of 4.8 mcg/kg as an IV infusion once a week in a 3-week cycle for the first 4 cycles (on Days 1, 8, and 15; each cycle duration=21 days) followed by once every 3 weeks (on Day 1) from Cycle 5 onwards until progressive disease, unacceptable AE, withdrawal of consent, lost to follow-up or death whichever occurs first.

Serious adverse events	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Superior vena cava syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			

Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Disease progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Pancytopenia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
Oesophagitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infections and infestations			
COVID-19			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (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 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	3 / 4 (75.00%)
number of deaths (all causes)	2	4	3
number of deaths resulting from	0	0	2

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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			
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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 exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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 / 4 (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			
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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			
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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
Cerebrovascular accident			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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 / 4 (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
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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 / 4 (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			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	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%)	0 / 4 (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 / 4 (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 / 4 (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	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)	4 / 6 (66.67%)	4 / 6 (66.67%)
number of deaths (all causes)	4	4	5
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour thrombosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Disease progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Fatigue			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	1 / 1	3 / 3	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Eye disorders			
Diplopia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Device related infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (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 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	5 / 14 (35.71%)	
number of deaths (all causes)	2	11	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Immune effector cell-associated neurotoxicity syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hyponatraemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Part 1A: BNT411 Monotherapy: Dose Level (DL) 1: 0.05 mcg/kg	Part 1A: BNT411 Monotherapy: DL2: 0.15 mcg/kg	Part 1A: BNT411 Monotherapy: DL3: 0.45 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Axillary pain			

subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	6	1	0
Pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Social avoidant behaviour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

C-reactive protein increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Liver function test increased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myopericarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Brain fog			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Leukopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye irritation			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	0	1	2
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
occurrences (all)	0	2	2
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Oliguria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1A: BNT411 Monotherapy: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL5: 2.4 mcg/kg	Part 1B: BNT411 Combination Dose: DL5: 2.4 mcg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	4 / 4 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Face oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			

Cytokine release syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Social avoidant behaviour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Investigations			
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2

Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Neutrophil count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Respiratory rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
White blood cells urine positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sinus bradycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myopericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Brain fog			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	3	1	1
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	3 / 4 (75.00%)
occurrences (all)	0	0	6
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Retinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	3
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 4 (25.00%)
occurrences (all)	0	1	1

Non-serious adverse events	Part 1A: BNT411 Monotherapy: DL6_2i: 6.0 mcg/kg	Part 1A: BNT411 Monotherapy: DL6_1i: 7.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL7: 9.6 mcg/kg
Total subjects affected by non-serious adverse events			

subjects affected / exposed	8 / 8 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	3	2
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 8 (25.00%)	3 / 6 (50.00%)	4 / 6 (66.67%)
occurrences (all)	7	22	30
Axillary pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Face oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	3 / 8 (37.50%)	3 / 6 (50.00%)	5 / 6 (83.33%)
occurrences (all)	10	8	7
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	3 / 8 (37.50%)	3 / 6 (50.00%)	2 / 6 (33.33%)
occurrences (all)	9	19	6
Pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	5 / 8 (62.50%)	3 / 6 (50.00%)	4 / 6 (66.67%)
occurrences (all)	8	17	16
Drug hypersensitivity			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Increased upper airway secretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Tachypnoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Delirium			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	2
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	2
Social avoidant behaviour			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Investigations			
Bacterial test positive			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 8 (37.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	3	0	5
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	1	1	3
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood potassium increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
C-reactive protein increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood calcium decreased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	4	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Blood fibrinogen decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Troponin I increased			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Weight decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Liver function test increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	1 / 6 (16.67%)
occurrences (all)	2	9	1
Neutrophil count decreased			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	0	7	2
Respiratory rate increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	6	0
White blood cells urine positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Sinus tachycardia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
Sinus bradycardia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myopericarditis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 8 (25.00%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	3	5	5
Dysgeusia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	4
Brain fog			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Neurotoxicity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	3
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	1	1

Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	3 / 6 (50.00%)
occurrences (all)	2	12	3
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Eye pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Meibomian gland dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Visual impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	3	2	1
Constipation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0

Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Nausea			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	5 / 6 (83.33%)
occurrences (all)	4	3	6
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 8 (25.00%)	3 / 6 (50.00%)	5 / 6 (83.33%)
occurrences (all)	6	5	5
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Night sweats			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Micturition urgency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	3 / 6 (50.00%)
occurrences (all)	1	4	5
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Coccydynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2

Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Hypomagnesaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	3 / 6 (50.00%)
occurrences (all)	1	4	4
Dehydration			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	1	4	3
Hypophosphataemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1B: BNT411 Combination Dose: DL4: 1.2 mcg/kg	Part 1A: BNT411 Monotherapy: DL6: 4.8 mcg/kg	
Total subjects affected by non-serious adverse events			

subjects affected / exposed	3 / 3 (100.00%)	14 / 14 (100.00%)	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	4	
General disorders and administration site conditions			
Energy increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	42	
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	6 / 14 (42.86%)	
occurrences (all)	1	8	
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	
occurrences (all)	1	1	
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	5 / 14 (35.71%)	
occurrences (all)	1	37	
Pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	3	
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	8	
Drug hypersensitivity			

subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 3 (66.67%)	2 / 14 (14.29%)	
occurrences (all)	2	2	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Increased upper airway secretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	2 / 3 (66.67%)	1 / 14 (7.14%)	
occurrences (all)	2	1	
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Pleuritic pain			

subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Social avoidant behaviour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Investigations			
Bacterial test positive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Aspartate aminotransferase increased				
subjects affected / exposed	1 / 3 (33.33%)	2 / 14 (14.29%)		
occurrences (all)	1	5		
Amylase increased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)		
occurrences (all)	1	0		
Alanine aminotransferase increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)		
occurrences (all)	0	3		
Activated partial thromboplastin time prolonged				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood potassium increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood potassium decreased				
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)		
occurrences (all)	1	0		
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)		
occurrences (all)	0	1		
C-reactive protein increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood creatinine increased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)		
occurrences (all)	0	2		
Blood calcium decreased				

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood bilirubin increased				
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)		
occurrences (all)	0	1		
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Blood fibrinogen decreased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Troponin I increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Weight decreased				
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)		
occurrences (all)	0	3		
Weight increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	2 / 3 (66.67%)	0 / 14 (0.00%)		
occurrences (all)	2	0		
International normalised ratio increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Liver function test increased				
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)		
occurrences (all)	0	0		
Lymphocyte count decreased				
subjects affected / exposed	2 / 3 (66.67%)	1 / 14 (7.14%)		
occurrences (all)	2	1		
Neutrophil count decreased				

subjects affected / exposed	2 / 3 (66.67%)	0 / 14 (0.00%)	
occurrences (all)	3	0	
Platelet count decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Respiratory rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 14 (0.00%)	
occurrences (all)	3	0	
White blood cells urine positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	5	
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Sinus bradycardia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Myopericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	3	
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Brain fog			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Paraesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	

Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 14 (7.14%)	
occurrences (all)	2	1	
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 14 (7.14%)	
occurrences (all)	2	1	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Meibomian gland dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Retinal exudates			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Retinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Vitreous detachment			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Visual field defect			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 14 (21.43%)	
occurrences (all)	1	3	
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	5 / 14 (35.71%)	
occurrences (all)	1	5	
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	

Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	2	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Lip dry			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

Nausea			
subjects affected / exposed	0 / 3 (0.00%)	8 / 14 (57.14%)	
occurrences (all)	0	9	
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 14 (21.43%)	
occurrences (all)	0	4	
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Oliguria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Lumbar spinal stenosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Coccydynia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Herpes simplex reactivation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Metabolism and nutrition disorders			
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 14 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 October 2019	A new protocol template was implemented, and inconsistencies in the previous protocol version were corrected.
07 May 2020	Some sections were rephrased for consistency and clarity, and a few country-specific modifications were made in assessments and safety reporting.
13 November 2020	A new version was implemented as there was a change in sponsor. Additionally, some corrections to timing of assessments and AE reporting were made.
01 July 2022	Backfilling of cohorts was introduced, and clarifications of trial procedures were made. Additionally, COVID-pandemic related specific modifications were made.
04 July 2023	Changes implemented in efficacy outcome measures to Part 2 of the trial only. The number of subjects were increased for Part 1A. End of trial definition was altered as follow-up for survival was removed.

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.

The planned Part 2 of the study was not conducted as the trial was terminated prematurely.

Notes: