



Clinical trial results:

First-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of W_pro1 (BNT112) monotherapy and in combination with cemiplimab in patients with prostate cancer

Summary

EudraCT number	2018-004321-86
Trial protocol	GB HU DE
Global end of trial date	23 January 2024

Results information

Result version number	v1
This version publication date	07 February 2025
First version publication date	07 February 2025

Trial information

Trial identification

Sponsor protocol code	RN5609C00
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04382898
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech SE, BioNTech SE, 0049 613190840, patients@biontech.de
Scientific contact	BioNTech SE, BioNTech SE, 0049 613190840, 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	10 May 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives for the study were:

For Part 1 and Part 2: To assess safety and tolerability profile of W_pro1 (BNT112-01) monotherapy or in combination with cemiplimab.

For Part 2 Arms 1a and 1b: To evaluate preliminary antitumor activity of W_pro1 (BNT112-01) monotherapy and in combination with cemiplimab in patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) based on objective response rate (ORR).

Protection of trial subjects:

The study was conducted 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	02 December 2019
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	United Kingdom: 23
Country: Number of subjects enrolled	United States: 12
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Hungary: 18
Worldwide total number of subjects	75
EEA total number of subjects	40

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)	26
From 65 to 84 years	48
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The trial consisted of 2 parts: Part 1 (dose titration) and Part 2 (dose expansion; consisted of four arms).

Pre-assignment

Screening details:

Part 1 and Part 2 (Arms 1A and 1B) enrolled subjects with metastatic castration-resistant prostate cancer (mCRPC). Part 2: Arms 2 and 3 enrolled subjects with newly diagnosed high-risk localized prostate cancer (LPC). A total of 75 subjects were enrolled in this study.

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 1 (mCRPC): BNT112

Arm description:

Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.

Arm type	Experimental
Investigational medicinal product name	BNT112
Investigational medicinal product code	BNT112
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

BNT112 administered as five slow IV bolus injections.

Arm title	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab
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Arm description:

Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.

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

Dosage and administration details:

Cemiplimab administered as IV infusion.

Investigational medicinal product name	BNT112
Investigational medicinal product code	BNT112
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

BNT112 administered as five slow IV bolus injections.

Arm title	Part 2 (mCRPC): Arm 1b: BNT112
Arm description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Arm type	Experimental
Investigational medicinal product name	BNT112
Investigational medicinal product code	BNT112
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

BNT112 administered as five slow IV injections.

Arm title	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Arm description: Subjects with high-risk, localised prostate cancer (LPC) received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 Q3W along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	
Arm type	Experimental
Investigational medicinal product name	BNT112
Investigational medicinal product code	BNT112
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

BNT112 administered as five slow IV injections.

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

Dosage and administration details:

Cemiplimab administered as IV infusion.

Arm title	Part 2 (LPC): Arm 3: BNT112
Arm description: Subjects with high-risk LPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	
Arm type	Experimental
Investigational medicinal product name	BNT112
Investigational medicinal product code	BNT112
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

BNT112 administered as five slow IV injections.

Number of subjects in period 1	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112
Started	9	28	27
Completed	2	10	9
Not completed	7	18	18
Consent withdrawn by subject	1	-	1
Study Terminated By Sponsor	-	1	1
Death	6	17	13
Progressive Disease	-	-	1
Unspecified	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 1	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab	Part 2 (LPC): Arm 3: BNT112
Started	5	6
Completed	4	5
Not completed	1	1
Consent withdrawn by subject	-	-
Study Terminated By Sponsor	-	1
Death	1	-
Progressive Disease	-	-
Unspecified	-	-
Lost to follow-up	-	-

Baseline characteristics

Reporting groups

Reporting group title	Part 1 (mCRPC): BNT112
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (mCRPC): Arm 1b: BNT112
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Reporting group description: Subjects with high-risk, localised prostate cancer (LPC) received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 Q3W along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	
Reporting group title	Part 2 (LPC): Arm 3: BNT112
Reporting group description: Subjects with high-risk LPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	

Reporting group values	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112
Number of subjects	9	28	27
Age categorical			
Units: Subjects			
< 50 years	0	0	0
>= 50 - < 65 years	1	7	11
>= 65 - < 85 years	8	20	16
>= 85 years	0	1	0
Gender categorical			
Units: Subjects			
Female	0	0	0
Male	9	28	27
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	8	27	26
More than one race	0	0	0

Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	4	0
Not Hispanic or Latino	9	23	27
Unknown or Not Reported	0	1	0

Reporting group values	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab	Part 2 (LPC): Arm 3: BNT112	Total
Number of subjects	5	6	75
Age categorical Units: Subjects			
< 50 years	0	0	0
>= 50 - < 65 years	3	4	26
>= 65 - < 85 years	2	2	48
>= 85 years	0	0	1
Gender categorical Units: Subjects			
Female	0	0	0
Male	5	6	75
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	1	5
White	3	5	69
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	4
Not Hispanic or Latino	4	6	69
Unknown or Not Reported	1	0	2

End points

End points reporting groups

Reporting group title	Part 1 (mCRPC): BNT112
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (mCRPC): Arm 1b: BNT112
Reporting group description: Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.	
Reporting group title	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Reporting group description: Subjects with high-risk, localised prostate cancer (LPC) received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 Q3W along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	
Reporting group title	Part 2 (LPC): Arm 3: BNT112
Reporting group description: Subjects with high-risk LPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.	

Primary: Part 1: Number of Subjects With Dose Limiting Toxicities (DLTs)

End point title	Part 1: Number of Subjects With Dose Limiting Toxicities (DLTs) ^{[1][2]}
End point description: DLT criteria were defined as following: any treatment-emergent adverse events (TEAE) of Grade 5 intensity; hematological toxicities (Grade 3 and 4 febrile neutropenia, Grade 4 thrombocytopenia, Grade 3 and 4 hemorrhage associated with thrombocytopenia of Grade greater than or equal to [\geq] 3, Grade 4 anemia); and non-hematological toxicities (Grade 4 cytokine release syndrome [CRS], Grade 3 CRS which has not improved to Grade 1 or resolved within 48 hours; any Grade \geq 3 non-hematological TEAE at least possibly related which occurs during the first BNT112 cancer vaccine treatment cycle). Analysis was performed on the DLT evaluation set that included all subjects who received IMP and completed the DLT evaluation period and met the minimum exposure criterion or experienced a DLT during 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 statistical testing was planned. [2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data for this endpoint was not planned to be collected and analysed for Part 2 arms due to early termination of the study.	

End point values	Part 1 (mCRPC): BNT112			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: subjects	2			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAEs Related to Trial Procedure

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Serious TEAEs and TEAEs Related to Trial Procedure ^[3]
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End point description:

TEAE: any adverse event (AE) with an onset date on or after the first administration of investigational medicinal product (IMP) or worsened after first administration of IMP. AEs with an onset date more than 30 days after last dose of BNT112 or 90 days after last dose of cemiplimab (Part 2: Arm 1a and Arm 2) were only considered as TEAEs if assessed as related to IMP by 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. 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; Grade 5: Death related to AE. Safety set.

End point type	Primary
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End point timeframe:

From Baseline up to 30 days after the last dose of BNT112 (for Part 1 and Part 2 Arms 1b and 3) or up to 90 days after the last dose of cemiplimab (for Part 2, Arm 1a and Arm 2) (up to 4 years and 1 month)

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 statistical testing was planned.

End point values	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	28	27	5
Units: subjects				
TEAEs	8	28	26	5
Serious TEAE	5	5	9	2
Grade \geq 3 TEAEs	7	15	15	1
Grade 5 TEAEs	2	0	1	0
TEAEs related to trial procedure	1	1	0	1

End point values	Part 2 (LPC): Arm 3: BNT112			
Subject group type	Reporting group			
Number of subjects analysed	6			

Units: subjects				
TEAEs	6			
Serious TEAE	2			
Grade ≥ 3 TEAEs	4			
Grade 5 TEAEs	0			
TEAEs related to trial procedure	2			

Statistical analyses

No statistical analyses for this end point

Primary: Part 2 Arm 1b: Objective Response Rate (ORR)

End point title	Part 2 Arm 1b: Objective Response Rate (ORR) ^{[4][5]}
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End point description:

ORR was defined as the percentage of subjects with a CR or PR as per PCWG3 criteria as determined by the investigator. Subjects not meeting the criteria for CR or PR, including those without any post-baseline tumor assessments, were considered as non-responders. CR was defined as the disappearance of all target lesions, with a reduction in short axis to <10 mm in any pathological lymph nodes and no new lesions. PR was defined as 30% decrease in the sum of the longest diameter of target lesions. Analysis was performed on mITT population.

End point type	Primary
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End point timeframe:

From start of treatment up to 104 weeks

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: Statistical Analysis data is added in chart form for ORR: Part 2: Arm 1b.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Data for this endpoint was not planned to be collected and analysed for Part 2: Arms 2 and 3.

End point values	Part 2 (mCRPC): Arm 1b: BNT112			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: percentage of subjects				
number (confidence interval 95%)	12.0 (2.5 to 31.2)			

Attachments (see zip file)	Statistical Analysis 1 for Part 2 Arms 1b/Statistical Analysis 1
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Statistical analyses

No statistical analyses for this end point

Primary: Part 2 Arms 1a: Objective Response Rate (ORR)

End point title	Part 2 Arms 1a: Objective Response Rate (ORR) ^{[6][7]}
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End point description:

ORR was defined as the percentage of subjects with a complete response (CR) or partial response (PR) as per Prostate Cancer Working Group 3 (PCWG3) criteria as determined by the investigator. Subjects not meeting the criteria for CR or PR, including those without any post-baseline tumor assessments, were considered as non-responders. CR was defined as the disappearance of all target lesions, with a reduction in short axis to <10 mm in any pathological lymph nodes and no new lesions. PR was defined as 30% decrease in the sum of the longest diameter of target lesions. Analysis was performed on modified Intent to Treat population (mITT) population that included all subjects who were randomised to the IMP and had a baseline and at least one post-baseline (i.e., one on-treatment or post-treatment) tumor assessment (clinical or imaging assessment).

End point type	Primary
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End point timeframe:

From start of treatment up to 46 weeks

Notes:

[6] - 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: Statistical Analysis data is added in chart form for ORR: Part 2: Arm 1a.

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Data for this endpoint was not planned to be collected and analysed for Part 2: Arms 2 and 3.

End point values	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 12.8)			

Attachments (see zip file)

Statistical Analysis 1 for Part 2 Arms 1a/Statistical Analysis 1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Change From Baseline in Prostate-specific Antigen (PSA) Levels

End point title	Number of Subjects Reporting Change From Baseline in Prostate-specific Antigen (PSA) Levels
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End point description:

Subjects blood samples were tested for levels of PSA to track the progression of prostate cancer. PSA decline categories of No decline, 0 to 25%, >25% to 50%, and >50% compared to baseline during treatment according to PCWG3 (as reported by the investigator) are reported in this endpoint. Analysis was performed on mITT population. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data for each specified category at respective visit and "99999" in the data field signifies that no subjects were available for analysis at the specified visit.

End point type	Secondary
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End point timeframe:

Day 8 (Cycles 1 and 2 only), Day 1 Cycle 2 and Day 15 (Cycles 1, 2 and 8 only) (each cycle of 21-days), and End of treatment ([EOT]; up to 24 months)

End point values	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	24	23	5
Units: subjects				
Cycle 1 Day 8: No decline (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 8: 0 to 25% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 8: Greater than(>) 25%- 50%(n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 8: >50% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 15: No decline (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 15: 0 to 25% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 15: > 25% to 50% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 15: > 50% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 2 Day 1: No decline (n=8,24,23,5,6)	6	21	19	1
Cycle 2 Day 1: 0 to 25% (n=8,24,23,5,6)	2	3	2	1
Cycle 2 Day 1: >25% to 50% (n=8,24,23,5,6)	0	0	1	0
Cycle 2 Day 1: >50% (n=8,24,23,5,6)	0	0	1	3
Cycle 2 Day 8: No decline (n=1,0,0,0,1)	1	99999	99999	99999
Cycle 2 Day 8: 0 to 25% (n=1,0,0,0,1)	0	99999	99999	99999
Cycle 2 Day 8: >25% to 50% (n=1,0,0,0,1)	0	99999	99999	99999
Cycle 2 Day 8: >50% (n=1,0,0,0,1)	0	99999	99999	99999
Cycle 2 Day 15: No decline (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 2 Day 15: 0 to 25% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 2 Day 15: >25% to 50% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 2 Day 15: >50% (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 8 Day 15: No decline (n=0,0,1,0,0)	99999	99999	1	99999
Cycle 8 Day 15: 0 to 25% (n=0,0,1,0,0)	99999	99999	0	99999
Cycle 8 Day 15: >25% to 50% (n=0,0,1,0,0)	99999	99999	0	99999
Cycle 8 Day 15: >50% (n=0,0,1,0,0)	99999	99999	0	99999
EOT: No decline (n=7,19,19,4,3)	7	17	19	0
EOT: 0 to 25% (n=7,19,19,4,3)	0	2	0	0
EOT: >25% to 50% (n=7,19,19,4,3)	0	0	0	0
EOT: >50% (n=7,19,19,4,3)	0	0	0	4

End point values	Part 2 (LPC): Arm 3: BNT112			
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Subject group type	Reporting group			
Number of subjects analysed	6			
Units: subjects				
Cycle 1 Day 8: No decline (n=0,0,0,0,1)	1			
Cycle 1 Day 8: 0 to 25% (n=0,0,0,0,1)	0			
Cycle 1 Day 8: Greater than(>) 25%-50% (n=0,0,0,0,1)	0			
Cycle 1 Day 8: >50% (n=0,0,0,0,1)	0			
Cycle 1 Day 15: No decline (n=0,0,0,0,1)	0			
Cycle 1 Day 15: 0 to 25% (n=0,0,0,0,1)	0			
Cycle 1 Day 15: > 25% to 50% (n=0,0,0,0,1)	1			
Cycle 1 Day 15: > 50% (n=0,0,0,0,1)	0			
Cycle 2 Day 1: No decline (n=8,24,23,5,6)	0			
Cycle 2 Day 1: 0 to 25% (n=8,24,23,5,6)	1			
Cycle 2 Day 1: >25% to 50% (n=8,24,23,5,6)	1			
Cycle 2 Day 1: >50% (n=8,24,23,5,6)	4			
Cycle 2 Day 8: No decline (n=1,0,0,0,1)	0			
Cycle 2 Day 8: 0 to 25% (n=1,0,0,0,1)	0			
Cycle 2 Day 8: >25% to 50% (n=1,0,0,0,1)	0			
Cycle 2 Day 8: >50% (n=1,0,0,0,1)	1			
Cycle 2 Day 15: No decline (n=0,0,0,0,1)	0			
Cycle 2 Day 15: 0 to 25% (n=0,0,0,0,1)	0			
Cycle 2 Day 15: >25% to 50% (n=0,0,0,0,1)	0			
Cycle 2 Day 15: >50% (n=0,0,0,0,1)	1			
Cycle 8 Day 15: No decline (n=0,0,1,0,0)	99999			
Cycle 8 Day 15: 0 to 25% (n=0,0,1,0,0)	99999			
Cycle 8 Day 15: >25% to 50% (n=0,0,1,0,0)	99999			
Cycle 8 Day 15: >50% (n=0,0,1,0,0)	99999			
EOT: No decline (n=7,19,19,4,3)	0			
EOT: 0 to 25% (n=7,19,19,4,3)	0			
EOT: >25% to 50% (n=7,19,19,4,3)	0			
EOT: >50% (n=7,19,19,4,3)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Change From Baseline in PSA Doubling Time (PSADT)

End point title	Number of Subjects Reporting Change From Baseline in PSA Doubling Time (PSADT)
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End point description:

Subjects blood samples were tested for levels of PSA to track the progression of prostate cancer. PSADT was calculated using a linear regression model of the natural logarithm of PSA values and time. PSA

doubling time compared to baseline during the treatment period for the following categories: 0 - 3 months; >3 - 6 months; >6 - 9 months; >9 - 12 months; >12 - 18 months; >18 - 24 months; >24 months and declining are reported in this endpoint. Analysis was performed on mITT population. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data for each specified category.

End point type	Secondary
End point timeframe:	
Cycle 4 Day 1, Cycle 8 Day 1, Cycle 12 Day 1 (each cycle duration=21 days)	

End point values	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	21	19	5
Units: subjects				
Cycle 4 Day 1: 0 - 3 months (n=6,21,19,5,5)	5	16	11	1
Cycle 4 Day 1: >3 - 6 months (n=6,21,19,5,5)	0	2	2	0
Cycle 4 Day 1: >6 - 9 months (n=6,21,19,5,5)	1	1	2	0
Cycle 4 Day 1: >9 - 12 months (n=6,21,19,5,5)	0	0	0	0
Cycle 4 Day 1: >12 - 18 months (n=6,21,19,5,5)	0	0	0	0
Cycle 4 Day 1: >18 - 24 months (n=6,21,19,5,5)	0	0	1	0
Cycle 4 Day 1: >24 months (n=6,21,19,5,5)	0	0	0	0
Cycle 4 Day 1: Declining (n=6,21,19,5,5)	0	2	3	4
Cycle 8 Day 1: 0 - 3 months (n=4,13,15,5,6)	3	6	8	0
Cycle 8 Day 1: >3 - 6 months (n=4,13,15,5,6)	0	5	1	0
Cycle 8 Day 1: >6 - 9 months (n=4,13,15,5,6)	0	1	0	0
Cycle 8 Day 1: >9 - 12 months (n=4,13,15,5,6)	0	0	2	0
Cycle 8 Day 1: >12 - 18 months (n=4,13,15,5,6)	0	0	1	0
Cycle 8 Day 1: >18 - 24 months (n=4,13,15,5,6)	0	0	0	0
Cycle 8 Day 1: >24 months (n=4,13,15,5,6)	1	0	1	0
Cycle 8 Day 1: Declining (n=4,13,15,5,6)	0	1	2	5
Cycle 12 Day 1: 0 - 3 months (n=3,7,6,4,3)	3	2	0	0
Cycle 12 Day 1: >3 - 6 months (n=3,7,6,4,3)	0	3	1	0
Cycle 12 Day 1: >6 - 9 months (n=3,7,6,4,3)	0	1	2	0
Cycle 12 Day 1: >9 - 12 months (n=3,7,6,4,3)	0	0	1	0
Cycle 12 Day 1: >12 - 18 months (n=3,7,6,4,3)	0	0	0	0

Cycle 12 Day 1: >18 - 24 months (n=3,7,6,4,3)	0	0	0	0
Cycle 12 Day 1: >24 months (n=3,7,6,4,3)	0	0	0	0
Cycle 12 Day 1: Declining (n=3,7,6,4,3)	0	1	2	4

End point values	Part 2 (LPC): Arm 3: BNT112			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: subjects				
Cycle 4 Day 1: 0 - 3 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >3 - 6 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >6 - 9 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >9 - 12 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >12 - 18 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >18 - 24 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: >24 months (n=6,21,19,5,5)	0			
Cycle 4 Day 1: Declining (n=6,21,19,5,5)	5			
Cycle 8 Day 1: 0 - 3 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >3 - 6 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >6 - 9 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >9 - 12 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >12 - 18 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >18 - 24 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: >24 months (n=4,13,15,5,6)	0			
Cycle 8 Day 1: Declining (n=4,13,15,5,6)	6			
Cycle 12 Day 1: 0 - 3 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >3 - 6 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >6 - 9 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >9 - 12 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >12 - 18 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >18 - 24 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: >24 months (n=3,7,6,4,3)	0			
Cycle 12 Day 1: Declining (n=3,7,6,4,3)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With PSA Decline of $\geq 50\%$

End point title	Number of Subjects With PSA Decline of $\geq 50\%$
End point description:	
Subjects blood samples were tested for levels of PSA to track the progression of prostate cancer. Subjects with PSA decline of $\geq 50\%$ compared to baseline according to PCWG3 (as reported by the investigator) are reported in this endpoint. Analysis was performed on mITT population. Here, "number of subjects analysed" = subjects with available data for this endpoint and "n" signifies subjects with available data for each specified category at respective visit and "99999" in the data field signifies that no subjects were available for analysis at the specified visit.	
End point type	Secondary
End point timeframe:	
Day 8 (Cycles 1 and 2 only), Day 1 Cycle 2 and Day 15 (Cycles 1, 2 and 8 only) of each 21-day cycle, and EOT (up to 24 months)	

End point values	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	24	23	5
Units: subjects				
Cycle 1 Day 8 (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 1 Day 15 (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 2 Day 1 (n=8,24,23,5,6)	0	0	1	3
Cycle 2 Day 8 (n=1,0,0,0,1)	0	99999	99999	99999
Cycle 2 Day 15 (n=0,0,0,0,1)	99999	99999	99999	99999
Cycle 8 Day 15 (n=0,0,1,0,0)	99999	99999	0	99999
EOT (n=7,19,19,4,3)	0	0	0	4

End point values	Part 2 (LPC): Arm 3: BNT112			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: subjects				
Cycle 1 Day 8 (n=0,0,0,0,1)	0			
Cycle 1 Day 15 (n=0,0,0,0,1)	0			
Cycle 2 Day 1 (n=8,24,23,5,6)	4			
Cycle 2 Day 8 (n=1,0,0,0,1)	1			
Cycle 2 Day 15 (n=0,0,0,0,1)	1			

Cycle 8 Day 15 (n=0,0,1,0,0) EOT (n=7,19,19,4,3)	99999 3			
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Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Arms 2 and 3: Number of Subjects With Tumor Response Post-Treatment

End point title	Part 2: Arms 2 and 3: Number of Subjects With Tumor Response Post-Treatment ^[8]
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End point description:

Best overall response was defined as single best response status at any tumor response assessment after first administration of IMP and prior to or at the start date of first subsequent anti-cancer therapy. Overall response of progressive disease within 14 days after the start date of first subsequent anti-cancer therapy was considered. The following order of tumor response categories were used, where "Complete Response" is best category: Complete Response (CR) – Partial Response (PR) – Stable Disease (SD) – Progressive Disease (PD) – Not Evaluable (NE) – Missing. CR: disappearance of all target lesions, with reduction in short axis to <10 mm in any pathological lymph nodes and no new lesions. PR: 30% decrease in the sum of the longest diameter of target lesions. PD: progression of target lesions (sum of diameter increase to nadir of ≥20% and by ≥5 mm), progression of existing non-target lesions, or appearance of 1 or more new lesions. SD: no evidence of PD, CR or PR. mITT population.

End point type	Secondary
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End point timeframe:

From start of treatment up to 25 weeks (Arm 2) and up to 26 weeks (Arm 3)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data for this endpoint was not planned to be collected and analysed for Part 1 and Part 2: Arms 1a and 1b.

End point values	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab	Part 2 (LPC): Arm 3: BNT112		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	6		
Units: subjects				
Complete Response (CR)	0	0		
Partial Response (PR)	3	3		
Stable Disease (SD)	2	2		
Progressive Disease (PD)	0	0		
Not Evaluable (NE)	0	0		
Missing	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Objective Response Rate (ORR)

End point title	Part 1: Objective Response Rate (ORR) ^[9]
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End point description:

ORR was defined as the percentage of subjects with a CR or PR as per PCWG3 criteria as determined by the investigator. Subjects not meeting the criteria for CR or PR, including those without any post-baseline tumor assessments, were considered as non-responders. CR was defined as the disappearance of all target lesions, with a reduction in short axis to <10 mm in any pathological lymph nodes and no new lesions. PR was defined as 30% decrease in the sum of the longest diameter of target lesions. Analysis was performed on mITT population.

End point type	Secondary
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End point timeframe:

From start of treatment up to 27 weeks

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Data for this endpoint was not planned to be collected and analysed for Part 2: Arms 2 and 3.

End point values	Part 1 (mCRPC): BNT112			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: percentage of subjects				
number (confidence interval 95%)	0 (0.0 to 33.6)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to 30 days after last dose of BNT112 (Part 1 & Part 2 Arms 1b & 3), or up to 90 days after last dose of cemiplimab (Part 2: Arm 1a & Arm 2) (up to 4 years and 1 month)

Adverse event reporting additional description:

Analysis was performed on safety set. 1 subject in Part 1 (mCRPC): BNT112 arm withdrew from study 13 days after receiving their last dose & is reported in participant flow section as having withdrawn from study (ITT population). The subject died within 30 days of their last dose so here included in the all-cause mortality count.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Part 1 (mCRPC): BNT112
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Reporting group description:

Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.

Reporting group title	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab
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Reporting group description:

Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.

Reporting group title	Part 2 (mCRPC): Arm 1b: BNT112
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Reporting group description:

Subjects with mCRPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression.

Reporting group title	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab
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Reporting group description:

Subjects with high-risk, localised prostate cancer (LPC) received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 Q3W along with cemiplimab IV Q3W for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.

Reporting group title	Part 2 (LPC): Arm 3: BNT112
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Reporting group description:

Subjects with high-risk LPC received IV administration of BNT112 on Days 1, 8 and 15 of Cycle 1 and Cycle 2, thereafter Q3W starting with Day 1 of Cycle 3 for each of the 21-days treatment cycles until unacceptable toxicity or disease progression, or up to Cycle 8 followed by radical prostatectomy.

Serious adverse events	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	5 / 28 (17.86%)	9 / 27 (33.33%)
number of deaths (all causes)	7	17	13
number of deaths resulting from adverse events	2	0	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	2 / 9 (22.22%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (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, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Electrocardiogram QT prolonged subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
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 / 9 (0.00%)	0 / 28 (0.00%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (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
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (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	2 / 9 (22.22%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 28 (0.00%)	0 / 27 (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
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (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			
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (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 / 9 (11.11%)	0 / 28 (0.00%)	0 / 27 (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
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 28 (0.00%)	0 / 27 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urethral obstruction			
subjects affected / exposed	1 / 9 (11.11%)	0 / 28 (0.00%)	0 / 27 (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
Ureteric obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pelvic abscess			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (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
Appendicitis perforated			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (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
Septic shock			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (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
Urinary tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab	Part 2 (LPC): Arm 3: BNT112	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 5 (40.00%)	2 / 6 (33.33%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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			
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Appendicitis perforated			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (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 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1 (mCRPC): BNT112	Part 2 (mCRPC): Arm 1a: BNT112 + Cemiplimab	Part 2 (mCRPC): Arm 1b: BNT112
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 9 (88.89%)	28 / 28 (100.00%)	26 / 27 (96.30%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 9 (44.44%)	4 / 28 (14.29%)	5 / 27 (18.52%)
occurrences (all)	11	6	21
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

Hypotension subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	3 / 27 (11.11%) 5
Flushing subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
General disorders and administration site conditions			
General physical health deterioration subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	0 / 27 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	10 / 28 (35.71%) 12	5 / 27 (18.52%) 6
Chills subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	16 / 28 (57.14%) 39	6 / 27 (22.22%) 22
Chest pain subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 28 (3.57%) 1	0 / 27 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 10	5 / 28 (17.86%) 7	5 / 27 (18.52%) 9
Asthenia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	2 / 27 (7.41%) 3
Pyrexia subjects affected / exposed occurrences (all)	6 / 9 (66.67%) 15	17 / 28 (60.71%) 31	16 / 27 (59.26%) 37
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	3 / 28 (10.71%) 3	2 / 27 (7.41%) 2
Injection site reaction subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Immune system disorders			

Cytokine release syndrome subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	0 / 28 (0.00%) 0	1 / 27 (3.70%) 5
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	1 / 27 (3.70%) 1
Hypoxia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	1 / 27 (3.70%) 1
Dyspnoea subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	4 / 28 (14.29%) 4	1 / 27 (3.70%) 2
Psychiatric disorders			
Insomnia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	3 / 28 (10.71%) 3	0 / 27 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	0 / 27 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	3 / 28 (10.71%) 3	0 / 27 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	2 / 27 (7.41%) 2
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 6	0 / 27 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	1 / 27 (3.70%) 1

Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	4 / 28 (14.29%) 4	1 / 27 (3.70%) 1
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 3	0 / 28 (0.00%) 0	2 / 27 (7.41%) 2
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	3 / 9 (33.33%) 3	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	3 / 28 (10.71%) 3	0 / 27 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	1 / 28 (3.57%) 1	2 / 27 (7.41%) 2
Lipase increased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	1 / 27 (3.70%) 1
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	0 / 27 (0.00%) 0
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	0 / 27 (0.00%) 0
Injury, poisoning and procedural complications Procedural pain subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 2	2 / 27 (7.41%) 26
Congenital, familial and genetic disorders Hypertrophic cardiomyopathy			

subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 9 (0.00%)	3 / 28 (10.71%)	0 / 27 (0.00%)
occurrences (all)	0	3	0
Tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	1 / 27 (3.70%)
occurrences (all)	0	3	1
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	1 / 27 (3.70%)
occurrences (all)	0	2	1
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	3 / 28 (10.71%)	1 / 27 (3.70%)
occurrences (all)	0	3	1
Headache			
subjects affected / exposed	1 / 9 (11.11%)	3 / 28 (10.71%)	2 / 27 (7.41%)
occurrences (all)	1	7	2
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	2 / 28 (7.14%)	1 / 27 (3.70%)
occurrences (all)	0	2	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 9 (44.44%)	8 / 28 (28.57%)	4 / 27 (14.81%)
occurrences (all)	5	8	4
Thrombocytopenia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 28 (7.14%)	1 / 27 (3.70%)
occurrences (all)	1	2	1
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Dry mouth			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	2 / 28 (7.14%)	0 / 27 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	4 / 9 (44.44%)	6 / 28 (21.43%)	6 / 27 (22.22%)
occurrences (all)	4	11	7
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 9 (11.11%)	3 / 28 (10.71%)	4 / 27 (14.81%)
occurrences (all)	1	4	6
Abdominal pain			
subjects affected / exposed	1 / 9 (11.11%)	2 / 28 (7.14%)	3 / 27 (11.11%)
occurrences (all)	1	6	4
Abdominal pain upper			
subjects affected / exposed	1 / 9 (11.11%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	1 / 9 (11.11%)	2 / 28 (7.14%)	6 / 27 (22.22%)
occurrences (all)	1	3	8
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	2 / 28 (7.14%)	3 / 27 (11.11%)
occurrences (all)	1	2	3
Skin and subcutaneous tissue disorders			
Urticaria			

subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Rash subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	0 / 27 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	0 / 27 (0.00%) 0
Night sweats subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	0 / 27 (0.00%) 0
Renal and urinary disorders Urinary incontinence subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	0 / 27 (0.00%) 0
Pyelocaliectasis subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 2	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Pollakiuria subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 28 (3.57%) 1	1 / 27 (3.70%) 1
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	2 / 28 (7.14%) 2	1 / 27 (3.70%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	4 / 28 (14.29%) 4	6 / 27 (22.22%) 7
Arthritis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	2 / 27 (7.41%) 3
Back pain			

subjects affected / exposed	2 / 9 (22.22%)	4 / 28 (14.29%)	3 / 27 (11.11%)
occurrences (all)	2	4	4
Bone pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Gouty arthritis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	2 / 27 (7.41%)
occurrences (all)	0	0	2
Mobility decreased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	2
Musculoskeletal chest pain			
subjects affected / exposed	1 / 9 (11.11%)	1 / 28 (3.57%)	1 / 27 (3.70%)
occurrences (all)	1	1	1
Myalgia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	1 / 28 (3.57%)	4 / 27 (14.81%)
occurrences (all)	0	4	5
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	1 / 28 (3.57%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	2 / 28 (7.14%)	1 / 27 (3.70%)
occurrences (all)	0	2	1
Coronavirus infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 28 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

COVID-19 subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	4 / 28 (14.29%) 4	5 / 27 (18.52%) 5
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	2 / 9 (22.22%) 2	2 / 28 (7.14%) 2	2 / 27 (7.41%) 2
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	1 / 27 (3.70%) 1
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	0 / 28 (0.00%) 0	0 / 27 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	1 / 28 (3.57%) 1	2 / 27 (7.41%) 3
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	0 / 28 (0.00%) 0	1 / 27 (3.70%) 3
Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 28 (3.57%) 1	1 / 27 (3.70%) 1

Non-serious adverse events	Part 2 (LPC): Arm 2: BNT112 + Cemiplimab	Part 2 (LPC): Arm 3: BNT112	
Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 5 (100.00%)	6 / 6 (100.00%)	
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	3 / 6 (50.00%) 4	
Hot flush subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 2	2 / 6 (33.33%) 2	
Hypotension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	

Flushing subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1	
General disorders and administration site conditions General physical health deterioration subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Fatigue subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	2 / 6 (33.33%) 2	
Chills subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	4 / 6 (66.67%) 5	
Chest pain subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Influenza like illness subjects affected / exposed occurrences (all)	3 / 5 (60.00%) 3	2 / 6 (33.33%) 2	
Asthenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Pyrexia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 3	2 / 6 (33.33%) 3	
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 6 (16.67%) 1	
Injection site reaction subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Immune system disorders Cytokine release syndrome subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1	
Hypoxia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 2	
Dyspnoea subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Anxiety subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1	
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
C-reactive protein increased subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0	
Blood pressure increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Amylase increased subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 6 (16.67%) 1	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0	
Blood creatinine increased			

subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences (all)	1	2	
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Atrial fibrillation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dizziness			
subjects affected / exposed	1 / 5 (20.00%)	2 / 6 (33.33%)	
occurrences (all)	1	3	
Headache			
subjects affected / exposed	2 / 5 (40.00%)	2 / 6 (33.33%)	
occurrences (all)	4	3	
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Dyspepsia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Toothache			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 6 (33.33%)	
occurrences (all)	0	2	
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	

Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Urinary incontinence			
subjects affected / exposed	2 / 5 (40.00%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Pyelocaliectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	1 / 5 (20.00%)	2 / 6 (33.33%)	
occurrences (all)	1	2	
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Arthritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Gouty arthritis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Joint swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Mobility decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Coronavirus infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
COVID-19			
subjects affected / exposed	0 / 5 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			

Decreased appetite subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 6 (0.00%) 0	
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0	
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0	
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 2	
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 6 (0.00%) 0	
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 6 (16.67%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 September 2019	A new protocol template was implemented, and inconsistencies in the previous protocol version were corrected.
05 March 2020	The dose-limiting toxicity section was updated, and inconsistencies in the previous protocol version were corrected.
01 October 2020	Amendment 3 implemented primarily cemiplimab-relevant information and changes reflecting feedback from the pre-IND meeting with the US Food and Drug Administration (FDA) regarding the newly diagnosed localized prostate cancer clinical setting. The company product code BNT112 for BNT112 cancer vaccine was introduced. Also, information relevant to Part 2 was corrected and actualized including the dose range confirmation.
06 April 2021	Amendment 4 implemented the option for patients with mCRPC on BNT112 monotherapy to switch to cemiplimab monotherapy after disease progression. Additional changes were incorporated following regulatory agency feedback.
23 February 2022	Amendment 5 included the following substantial changes: Change of the immunogenicity secondary endpoint to an exploratory endpoint; Additional exclusion criterion regarding mentally incapacitated patients, as previously requested by the United States and German authorities; Schedule of Assessments was adapted to allow for additional blood draws at C1D8, C1D15, C2D8, and C2D15 for prostate-specific antigen level assessment. Other changes included a terminology change from W_pro1 to BNT112 and the correction of inconsistencies.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported