Clinical trial results:
A Phase 2, Open-label, Randomized Controlled Trial of BMS-986218 or BMS-986218 Plus Nivolumab in Combination with Docetaxel in Participants with Metastatic Castration-resistant Prostate Cancer

Summary

EudraCT number	2021-003990-74
Trial protocol	ES GR
Global end of trial date	13 December 2023

Results information

Result version number	v1 (current)
This version publication date	07 December 2024
First version publication date	07 December 2024

Trial information

Trial identification

Sponsor protocol code	CA022-009

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 December 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 December 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the safety, tolerability, and DLTs of docetaxel in combination with BMS-986218 or in combination with BMS-986218 plus nivolumab in participants with mCRPC

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 Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 February 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 10
Worldwide total number of subjects	10
EEA total number of subjects	0

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)	4
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

10 Participants Enrolled and Treated

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment 1

Arm description:

BMS-986218 30mg Q3W + Docetaxel 75 mg/m² Q3W

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

Dosage and administration details:

75 mg/m² Q3W

Investigational medicinal product name	BMS-986218
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

30mg Q3W

Arm title	Treatment 2

Arm description:

BMS-986218 50mg Q3W + Docetaxel 75 mg/m² Q3W

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

Dosage and administration details:

75 mg/m² Q3W

Investigational medicinal product name	BMS-986218
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:
50mg Q3W

Number of subjects in period 1	Treatment 1	Treatment 2
Started	3	7
Completed	1	0
Not completed	2	7
Participant request to discontinue treatment	-	1
Physician decision	-	1
Adverse event, non-fatal	1	3
Progressive Disease	1	1
Other Reason	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Treatment 1
Reporting group description:	
BMS-986218 30mg Q3W + Docetaxel 75 mg/m² Q3W	
Reporting group title	Treatment 2
Reporting group description:	
BMS-986218 50mg Q3W + Docetaxel 75 mg/m² Q3W	

Reporting group values	Treatment 1	Treatment 2	Total
Number of subjects	3	7	10
Age categorical Units: Subjects			
Adults (18-64 years)	1	3	4
From 65-84 years	2	4	6
Age Continuous Units: Years			
arithmetic mean	68.3	65.7	
standard deviation	± 6.11	± 9.14	-
Sex: Female, Male Units: Participants			
Female	0	0	0
Male	3	7	10
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	6	9
More than one race	0	0	0
Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	2	6	8
Unknown or Not Reported	0	1	1

End points

End points reporting groups

Reporting group title	Treatment 1
Reporting group description: BMS-986218 30mg Q3W + Docetaxel 75 mg/m² Q3W	
Reporting group title	Treatment 2
Reporting group description: BMS-986218 50mg Q3W + Docetaxel 75 mg/m² Q3W	

Primary: Number of Participants with Treatment related Adverse Events

End point title	Number of Participants with Treatment related Adverse
End point description: Adverse events will presetned using National Cancer Institute Common Terminology Criteria for Adverse Events version 5 (NCI CTCAE v5).	
End point type	Primary
End point timeframe: From first dose to 100 days follow up to last dose (Approximately 22 months)	

Notes:

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

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Participants	3	7		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment related Serious Adverse Events

End point title	Number of Participants with Treatment related Serious Adverse Events[2]
End point description: Adverse events will presetned using National Cancer Institute Common Terminology Criteria for Adverse Events version 5 (NCI CTCAE v5).	
End point type	Primary
End point timeframe: From first dose to 100 days follow up to last dose (Approximately 22 months)	

Notes:

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

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Participants	1	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Dose Limiting Toxicities

End point title	Number of Participants with Dose Limiting Toxicities[3]

End point description:

DLTs will be definied as:
Any treatment-related AEs for which a participant permanently discontinues a study treatment (other than daily prednisone) and that occurs during the first 2 cycles of treatment.
Any death not clearly due to the underlying disease or extraneous causes and that occurs during the first 2 cycles of treatment
Greater than or equal to Grade 2 pneumonitis lasting greater than 5 days despite appropriate medical therapy and that occurs during the first 2 cycles of treatment
Any neutropenic fever as well as Grade 4 neutropenia or thrombocytopenia for > 7 days that occurs during the first 2 cycles of treatment
Any treatment-related AE that delays initiation of Cycle 2 or Cycle 3 of treatment by greater than 2 consecutive weeks.

End point type	Primary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 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: No statistical analysis done for this endpoint

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Participants	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with AEs leading to discontinuation

End point title	Number of Participants with AEs leading to discontinuation[4]

End point description:

Adverse events will presetned using National Cancer Institute Common Terminology Criteria for Adverse Events version 5 (NCI CTCAE v5).

End point type	Primary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

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: No statistical analysis done for this endpoint

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Participants	2	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who died

End point title	Number of Participants who died[5]

End point description:

Number of participant deaths

End point type	Primary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

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: No statistical analysis done for this endpoint

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Participants	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate

End point title	Objective Response Rate

End point description:

Objective response rate per PCWG3 (ORR-PCWG3) is the proportion of participants who have a confirmed complete or partial best overall response (BOR) per PCWG3 among randomized participants who have measurable disease at baseline. The BOR is defined as the best response designation, as determined by the BICR, recorded between the date of randomization and the date of objectively documented radiographic progression, or last tumor measurement, whichever occurs first.

End point type	Secondary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[6]	0[7]		
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	(to)		

Notes:

[6] - No subjects Analyzed for this endpoint

[7] - No subjects Analyzed for this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Prostate Specific Antigen Response Rate (PSA-RR)

End point title	Prostate Specific Antigen Response Rate (PSA-RR)

End point description:

PSA-RR is the proportion of randomized participants with a 50% or greater decrease in PSA from baseline to any post-baseline PSA result. A second consecutive value obtained 3 or more weeks later is required to confirm the PSA response.

End point type	Secondary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Percentage of Participants				
number (confidence interval 95%)				
Unconfirmed or Confirmed PSA responders	33.3 (0.8 to 90.6)	57.1 (18.4 to 90.1)		
Confirmed PSA responders	33.3 (0.8 to 90.6)	57.1 (18.4 to 90.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response

End point description:

Duration of response per PCWG3 (DOR-PCWG3) is the time between the date of first response (CR/PR per PCWG3) to the date of first documented radiographic progression per PCWG3 (as determined by BICR), or death due to any cause.

End point type	Secondary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[8]	0[9]		
Units: Months				
median (full range (min-max))	(to)	(to)		

Notes:

[8] - No subjects Analyzed for this endpoint

[9] - No subjects Analyzed for this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Response

End point title	Time to Response

End point description:

Time to response per PCWG3 (TTR-PCWG3) is the time from randomization date to the date of the first documented CR or PR per PCWG3, as determined by BICR.

End point type	Secondary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[10]	0[11]		
Units: Months				
median (full range (min-max))	(to)	(to)		

Notes:

[10] - No subjects Analyzed for this endpoint

[11] - No subjects Analyzed for this endpoint

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival

End point description:

OS for all randomized participants is the time between randomization date and the date of death from any cause.

End point type	Secondary

End point timeframe:

From first dose to 100 days follow up to last dose (Approximately 22 months)

End point values	Treatment 1	Treatment 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[12]	0[13]		
Units: Percentage of Participants				
number (confidence interval 95%)	(to)	(to)		

Notes:

[12] - No subjects Analyzed for this endpoint

[13] - No subjects Analyzed for this endpoint

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events and Serious Adverse Events: (From first dose to last dose + 100 days): Approximately 22 Months

All-Cause mortality (From randomization to end of study): Approximately 22 Months.

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality represents all Randomized Participants. The number at Risk for Serious Adverse Events and Other (Not Including Serious) Adverse Events represents all participants that received at least 1 dose of study medication

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Treatment 1

Reporting group description:

BMS-986218 30mg Q3W + Docetaxel 75 mg/m² Q3W

Reporting group title	Treatment 2

Reporting group description:

BMS-986218 50mg Q3W + Docetaxel 75 mg/m² Q3W

Serious adverse events	Treatment 1	Treatment 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	6 / 7 (85.71%)	
number of deaths (all causes)	2	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Vasculitis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
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 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Metabolic encephalopathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Rectal abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Enterocolitis infectious			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Treatment 1	Treatment 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	7 / 7 (100.00%)	
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	5 / 7 (71.43%)	
occurrences (all)	0	11	
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	2	
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Chills			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	4 / 7 (57.14%)	
occurrences (all)	3	4	
Generalised oedema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 7 (57.14%)	
occurrences (all)	0	5	
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	
occurrences (all)	1	3	
Mucosal inflammation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	6	0	
Malaise			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Localised oedema			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Terminal agitation			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	4	0	
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Respiratory, thoracic and mediastinal disorders			
Pulmonary oedema			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Laryngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Epistaxis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	2	
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	2	2	
Sleep apnoea syndrome			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Respiratory failure			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	3	
Influenza A virus test positive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	2	
Blood creatinine increased			

subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	2	2	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	2	
Mycobacterium tuberculosis complex test positive			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	2	
Nitrite urine present			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Platelet count decreased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 7 (14.29%)	
occurrences (all)	2	2	
Prostatic specific antigen increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	2	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Infusion related reaction			

subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	
occurrences (all)	0	3	
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	
occurrences (all)	1	3	
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	2	
Blood and lymphatic system disorders			
Blood loss anaemia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	4 / 7 (57.14%)	
occurrences (all)	1	4	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Eye disorder			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	3	
Colitis			
subjects affected / exposed	1 / 3 (33.33%)	4 / 7 (57.14%)	
occurrences (all)	1	5	
Bowel movement irregularity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	
occurrences (all)	0	4	
Proctitis			

subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	2	
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	5 / 7 (71.43%)	
occurrences (all)	1	8	
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	2	
Haematochezia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	1	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Enterocolitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Dysphagia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	3 / 3 (100.00%)	4 / 7 (57.14%)	
occurrences (all)	3	11	
Skin and subcutaneous tissue disorders			

Skin ulcer				
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)		
occurrences (all)	1	1		
Skin exfoliation				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		
Skin disorder				
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)		
occurrences (all)	1	0		
Rash maculo-papular				
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)		
occurrences (all)	1	3		
Rash macular				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		
Rash				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		
Pruritus				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		
Night sweats				
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)		
occurrences (all)	1	0		
Nail discolouration				
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)		
occurrences (all)	1	0		
Erythema				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		
Alopecia				
subjects affected / exposed	2 / 3 (66.67%)	3 / 7 (42.86%)		
occurrences (all)	2	3		
Skin hyperpigmentation				
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)		
occurrences (all)	0	1		

Renal and urinary disorders			
Urethral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Cystitis noninfective			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Acute kidney injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	
occurrences (all)	0	3	
Back pain			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	
occurrences (all)	2	0	
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	2	

Neck pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Sacral pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	5	
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Rectal abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Staphylococcal skin infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Submandibular abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	2	
Tooth infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	3	
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	2	1	
Hypercalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Hypermagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	
occurrences (all)	1	0	
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	
occurrences (all)	0	1	
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	
occurrences (all)	1	2	
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	
occurrences (all)	0	3	
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	3 / 7 (42.86%)	
occurrences (all)	1	8	
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	
occurrences (all)	1	3	

Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 7 (28.57%) 3	
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	4 / 7 (57.14%) 6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 February 2022	The overall purpose for Protocol Amendment 02 is to introduce information regarding BMS- 986288, an additional "next-generation" anti-cytotoxic T-lymphocyte-associated protein 4 (anti- CTLA-4) monoclonal antibody (mAb). BMS-986288 may be incorporated into the study design via future protocol amendment to test further the central study hypothesis that addition of nextgeneration anti-CTLA-4 agents, with or without nivolumab, will improve outcomes compared to docetaxel alone. BMS-986288 is another non-fucosylated next-generation anti-CTLA-4 that shares the Fcγ receptor (FcγR)-dependent mechanisms of BMS-986218. BMS-986288 is identical to BMS-986218 except for an additional "Probody" design element that could decrease toxicity by preventing binding to sites outside of the tumor, and thus further improve the benefit/risk profile as compared to BMS-986218. An update was also made to the Bayesian Optimal Interval (BOIN) table that eliminated criteria for 1 or 2 participants, as enrollment will be in groups of 3 to 4 participants at a time in Part 1a and Part 1b.

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.

This study was terminated early after the safety lead-in portion (Part 1).

Notes: