Clinical trial results:
A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants with Advanced Renal Cell Carcinoma (FRACTION-RCC)

Summary

EudraCT number	2016-003082-26
Trial protocol	AT IT
Global end of trial date	23 November 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	CA018-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02996110
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, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb International Corporation, 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	16 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy (objective response rate (ORR), duration of response (DOR), and progression-free survival rate (PFSR) at 24-weeks) of each FRACTION-RCC study treatment combination (relative to nivolumab in combination with ipilimumab, when applicable) in participants with advanced renal cell carcinoma (RCC).

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2017
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	Australia: 12
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	Israel: 13
Country: Number of subjects enrolled	Italy: 18
Country: Number of subjects enrolled	United States: 120
Worldwide total number of subjects	182
EEA total number of subjects	20

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)	120
From 65 to 84 years	62
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

178 participants total were treated in the study. 60 were initially randomized and received treatment in Track 1. 118 were initially randomized to Track 2 but 152 participants in total were treated in track 2 due to 35 participants from either track 1 or 2 being re-randomized to receive a different treatment combination in Track 2.

Period 1

Period 1 title	Pre-Treatment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)

Arm description:

Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg IV infusion every 3 weeks for 4 doses

Investigational medicinal product name	Ipilimumab (BMS-734016)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 1 mg/kg every three weeks for 4 doses

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Arm title	Arm 2: Nivolumab plus Relatlimab (BMS-986016)

Arm description:

Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of

approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 240-mg flat dose via IV infusion every 2 weeks

Investigational medicinal product name	Relatlimab (BMS-986016-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986016 80 mg administered IV approximately 60 minutes every two weeks

Arm title	Arm 3: Nivolumab plus BMS-986205

Arm description:

Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-986205
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Capsule
Routes of administration	Oral use

Dosage and administration details:

BMS-986205 at a dose of 100 mg per day following a meal

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Arm title	Arm 4: Nivolumab plus BMS-813160 150 mg

Arm description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

BMS-813160 taken orally at 150 mg daily

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Arm title	Arm 5: Nivolumab plus BMS-813160 300mg

Arm description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

BMS-813160 taken orally at 300 mg daily

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Number of subjects in period 1	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)	Arm 2: Nivolumab plus Relatlimab (BMS-986016)	Arm 3: Nivolumab plus BMS-986205
Started	65	56	26
Completed	65	55	25
Not completed	0	1	1
Other Reasons	-	1	-
Participant Withdrew Consent	-	-	1

Number of subjects in period 1	Arm 4: Nivolumab plus BMS-813160 150 mg	Arm 5: Nivolumab plus BMS-813160 300mg
Started	17	18
Completed	17	16
Not completed	0	2
Other Reasons	-	1
Participant Withdrew Consent	-	1

Period 2

Period 2 title	Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)

Arm description:

Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 3 mg/kg IV infusion every 3 weeks for 4 doses

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Investigational medicinal product name	Ipilimumab (BMS-734016)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 1 mg/kg every three weeks for 4 doses

Arm title	Arm 2: Nivolumab plus Relatlimab (BMS-986016)

Arm description:

Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental

Investigational medicinal product name	Relatlimab (BMS-986016-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986016 80 mg administered IV approximately 60 minutes every two weeks

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 240-mg flat dose via IV infusion every 2 weeks

Arm title	Arm 3: Nivolumab plus BMS-986205

Arm description:

Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-986205
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Capsule
Routes of administration	Oral use

Dosage and administration details:

BMS-986205 at a dose of 100 mg per day following a meal

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Arm title	Arm 4: Nivolumab plus BMS-813160 150 mg

Arm description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

BMS-813160 taken orally at 150 mg daily

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Arm title	Arm 5: Nivolumab plus BMS-813160 300mg

Arm description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	BMS-813160
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Tablet
Routes of administration	Oral use

Dosage and administration details:

BMS-813160 taken orally at 300 mg daily

Investigational medicinal product name	Nivolumab (BMS-936558-01)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 480 mg by IV infusion every 4 weeks

Number of subjects in period 2[1]	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)	Arm 2: Nivolumab plus Relatlimab (BMS-986016)	Arm 3: Nivolumab plus BMS-986205
Started	65	55	25
Completed	4	3	1
Not completed	72	59	30
Consent withdrawn by subject	1	2	3
Completed treatment in Track 1	7	8	-
Other Reasons	-	-	1
Death	-	-	1
Subject Request to Discontinue Treatment	1	-	2
Subject No Longer Meets Study Criteria	1	-	-
Adverse Event Unrelated to Study Drug	5	1	-
Study Drug Toxicity	9	4	4
Disease Progression	48	43	19
Administrative Reason by Sponsor	-	1	-
Joined	11	7	6

Transferred in from other group/arm	11	7	6

Number of subjects in period 2[1]	Arm 4: Nivolumab plus BMS-813160 150 mg	Arm 5: Nivolumab plus BMS-813160 300mg
Started	17	16
Completed	1	1
Not completed	20	21
Consent withdrawn by subject	1	1
Completed treatment in Track 1	-	-
Other Reasons	-	1
Death	-	1
Subject Request to Discontinue Treatment	1	2
Subject No Longer Meets Study Criteria	-	-
Adverse Event Unrelated to Study Drug	1	1
Study Drug Toxicity	1	-
Disease Progression	16	15
Administrative Reason by Sponsor	-	-
Joined	4	6
Transferred in from other group/arm	4	6

Notes:

[1] - The number of subjects transferring in and out of the arms in the period are not the same. It is expected the net number of transfers in and out of the arms in a period, will be zero.
Justification: 35 participants from either Track 1 or 2 were re-randomized to receive a different treatment combination in Track 2

Baseline characteristics

Reporting groups	
Reporting group title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)
Reporting group description:	
Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.	
Reporting group title	Arm 2: Nivolumab plus Relatlimab (BMS-986016)
Reporting group description:	
Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.	
Reporting group title	Arm 3: Nivolumab plus BMS-986205
Reporting group description:	
Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.	
Reporting group title	Arm 4: Nivolumab plus BMS-813160 150 mg
Reporting group description:	
Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.	
Reporting group title	Arm 5: Nivolumab plus BMS-813160 300mg
Reporting group description:	
Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.	

Reporting group values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)	Arm 2: Nivolumab plus Relatlimab (BMS-986016)	Arm 3: Nivolumab plus BMS-986205
Number of subjects	65	56	26
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	40	41	16
>=65 years	25	15	10
Age continuous Units: years			
arithmetic mean	61.1	57.4	60.8
standard deviation	± 9.8	± 9.7	± 11.6
Sex: Female, Male Units: Participants			
Female	14	16	6
Male	51	40	20

Race/Ethnicity, Customized Units: Subjects			
White	62	52	23
Asian Indian	1	0	0
Chinese	0	1	0
Asian Other	1	1	0
Other	1	2	2
Black or African American	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	2	2
Not Hispanic or Latino	37	34	19
Unknown or Not Reported	25	20	5

Reporting group values	Arm 4: Nivolumab plus BMS-813160 150 mg	Arm 5: Nivolumab plus BMS-813160 300mg	Total
Number of subjects	17	18	182
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	12	11	120
>=65 years	5	7	62
Age continuous Units: years			
arithmetic mean	57.6	61.1	
standard deviation	± 11.4	± 12.0	-
Sex: Female, Male Units: Participants			
Female	4	9	49
Male	13	9	133
Race/Ethnicity, Customized Units: Subjects			
White	14	17	168
Asian Indian	0	0	1
Chinese	0	0	1
Asian Other	0	0	2
Other	2	0	7
Black or African American	1	1	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	8
Not Hispanic or Latino	12	10	112
Unknown or Not Reported	4	8	62

End points

End points reporting groups

Reporting group title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)

Reporting group description:

Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 2: Nivolumab plus Relatlimab (BMS-986016)

Reporting group description:

Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 3: Nivolumab plus BMS-986205

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 4: Nivolumab plus BMS-813160 150 mg

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 5: Nivolumab plus BMS-813160 300mg

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016)

Reporting group description:

Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 2: Nivolumab plus Relatlimab (BMS-986016)

Reporting group description:

Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 3: Nivolumab plus BMS-986205

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 4: Nivolumab plus BMS-813160 150 mg

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Reporting group title	Arm 5: Nivolumab plus BMS-813160 300mg

Reporting group description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Subject analysis set title	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)
Subject analysis set type	Full analysis

Subject analysis set description:

Nivolumab was administered at 3 mg/kg via IV infusion followed by ipilimumab 1 mg/kg administered IV over approximately 30 minutes every 3 weeks for 4 doses. Six weeks after the last dose of combination study treatment nivolumab 480 mg was administered IV over approximately 30 minutes every 4 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Subject analysis set title	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)
Subject analysis set type	Full analysis

Subject analysis set description:

Nivolumab was administered at a flat dose of 240 mg via IV infusion every 2 weeks followed by 80 mg BMS-986016 administered IV approximately 60 minutes every 2 weeks until completion of approximately 2 years of study treatment, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Subject analysis set title	Arm 3: Nivolumab plus BMS-986205 (Experimental)
Subject analysis set type	Full analysis

Subject analysis set description:

Nivolumab was administered as a flat dose of 480 mg via IV infusion every 4 weeks, and BMS-986205 taken orally at a dose of 100 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Subject analysis set title	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject analysis set type	Full analysis

Subject analysis set description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 150 mg daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Subject analysis set title	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)
Subject analysis set type	Full analysis

Subject analysis set description:

Nivolumab was administered as a flat dose of 480 mg by IV infusion every 4 weeks combined with oral BMS-813160, 300 mg twice daily for up to 2 years, clinical deterioration suggesting that no further benefit from study treatment is likely, intolerable toxicity, meeting of criteria for discontinuation of study treatment, or withdrawal of consent, whichever occurred first.

Primary: Objective Response Rate (ORR) per Investigator

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

End point description:

ORR is percent of participants whose best overall response (BOR) is complete response (CR) or partial response (PR).
BOR is the best response from the start of the study treatment until objectively documented progression per RECIST v1.1 or subsequent anticancer therapy, whichever occurs first.
For participants who received re-treatment or were re-randomized, the re-treatment and re-randomized

therapies were considered subsequent anticancer therapy.
CR is the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) have reduction in short axis to <10 mm.
PR is at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
The Response Evaluation Criteria in Solid Tumors (RECIST) is a standard way to measure the response of a tumor to treatment.
CR+PR, confidence interval based on Clopper and Pearson method. 99999 =Not-Applicable/Available

End point type	Primary

End point timeframe:

From first dose of study treatment until progression or subsequent anticancer therapy, whichever occurs first (assessed up to approximately 247 weeks)

Notes:

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

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Percent of participants				
number (confidence interval 95%)				
Track 1	20 (7.7 to 38.6)	30 (14.7 to 49.4)	99999 (99999 to 99999)	99999 (99999 to 99999)
Track 2	17.4 (7.8 to 31.4)	3.1 (0.1 to 16.2)	3.2 (0.1 to 16.7)	9.5 (1.2 to 30.4)

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Percent of participants				
number (confidence interval 95%)				
Track 1	99999 (99999 to 99999)			
Track 2	0.0 (0.0 to 15.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Median Duration of Response (DOR) per Investigator

End point title	Median Duration of Response (DOR) per Investigator[2]

End point description:

Duration of Response is defined as the time between the date of first response and the date of first

documented disease progression as determined by RECIST 1.1 or death due to any cause (death occurring after re-treatment or randomization to new combination treatment was not considered), whichever occurred first.
Complete Response (CR) is the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.
Partial Response (PR) is at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
Median computed using Kaplan -Meier method. 99999 = Not-Applicable

End point type	Primary

End point timeframe:

Time between the date of first response and the date of first documented disease progression or death due to any cause (assessed from an average of 22 weeks up to approximately 140 weeks).

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: Only summary statistics were planned for this endpoint.

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	10	1	2
Units: Weeks				
median (full range (min-max))				
Track 1	99999 (99999 to 99999)	32.57 (0.1 to 52.6)	99999 (99999 to 99999)	99999 (99999 to 99999)
Track 2	68.00 (0.1 to 117.6)	99.4 (99.4 to 99.4)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[3]			
Units: Weeks				
median (full range (min-max))				
Track 1	(to)			
Track 2	(to)			

Notes:

[3] - No participants had a response to treatment

Statistical analyses

No statistical analyses for this end point

Primary: Progression Free Survival Rate (PFSR) at 24 Weeks.

End point title	Progression Free Survival Rate (PFSR) at 24 Weeks.[4]

End point description:

The PFSR at 24 weeks is defined as the proportion of treated participants remaining progression free and surviving at 24 weeks since the first dosing date. Progressive Disease (PD) is at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this

includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
Point estimates are derived from Kaplan-Meier analyses, the 95% CIs are derived from Greenwood formula. 99999 = Not Applicable/Available

End point type	Primary

End point timeframe:

24 weeks after first treatment dose.

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: Only summary statistics were planned for this endpoint

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Proportion of participants				
number (confidence interval 95%)				
Track 1	0.491 (0.294 to 0.661)	0.429 (0.246 to 0.600)	99999 (99999 to 99999)	99999 (99999 to 99999)
Track 2	0.432 (0.277 to 0.577)	0.194 (0.079 to 0.346)	0.278 (0.118 to 0.464)	0.468 (0.237 to 0.670)

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Proportion of participants				
number (confidence interval 95%)				
Track 1	99999 (99999 to 99999)			
Track 2	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs)

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 118 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Participants				
Track 1	29	30	99999	99999
Track 2	45	32	31	19

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Participants				
Track 1	99999			
Track 2	21			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Adverse Events (SAEs)

End point title	Number of Participants with Serious Adverse Events (SAEs)

End point description:

Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires inpatient hospitalization or causes prolongation of existing hospitalization. 99999 = Not Available/Applicable

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 118 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Participants				
Track 1	17	15	99999	99999
Track 2	28	16	16	9

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Participants				
Track 1	99999			
Track 2	15			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 118 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Participants				
Track 1	7	7	99999	99999
Track 2	10	3	6	2

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Participants				
Track 1	99999			
Track 2	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Died

End point title	Number of Participants who Died

End point description:

Death is defined as the cessation of all vital functions of the body including the heartbeat, brain activity (including the brain stem), and breathing. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 118 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	76	62	31	21
Units: Participants				
Track 1	12	15	99999	99999
Track 2	27	17	13	10

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Participants				
Track 1	99999			

Track 2	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Thyroid Test Results - Track 1

End point title	Number of Participants with Abnormal Thyroid Test Results - Track 1

End point description:

The number of participants with laboratory abnormalities in specific thyroid tests based on SI conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 30 days after last dose of study therapy (approximately 108 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	27	0[5]	0[6]
Units: Participants				
TSH > ULN	8	8		
TSH > ULN WITH TSH <= ULN AT BASELINE	5	8		
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	3	3		
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	3	2		
TSH > ULN WITH FT3/FT4 TEST MISSING	2	3		
TSH < LLN	10	5		
TSH <LLN WITH TSH >= LLN AT BASELINE	9	5		
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	3	0		
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	2	1		
TSH < LLN WITH FT3/FT4 TEST MISSING	5	4		

Notes:

[5] - No Track 1

[6] - No Track 1

End point values	Arm 5: Nivolumab plus BMS-813160			

	300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[7]			
Units: Participants				
TSH > ULN				
TSH > ULN WITH TSH <= ULN AT BASELINE				
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN				
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN				
TSH > ULN WITH FT3/FT4 TEST MISSING				
TSH < LLN				
TSH <LLN WITH TSH >= LLN AT BASELINE				
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN				
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN				
TSH < LLN WITH FT3/FT4 TEST MISSING				

Notes:

[7] - No Track 1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Thyroid Test Results - Track 2

End point title	Number of Participants with Abnormal Thyroid Test Results - Track 2

End point description:

The number of participants with laboratory abnormalities in specific thyroid tests based on SI conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 30 days after last dose of study therapy (approximately 108 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	30	25	17
Units: Participants				
TSH > ULN	14	14	6	3
TSH > ULN WITH TSH <= ULN AT BASELINE	8	6	3	2
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	5	3	1	1

TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	5	4	3	2
TSH > ULN WITH FT3/FT4 TEST MISSING	4	7	2	0
TSH < LLN	4	5	2	2
TSH <LLN WITH TSH >= LLN AT BASELINE	2	4	1	2
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	1	0	1	1
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0	3	0	0
TSH < LLN WITH FT3/FT4 TEST MISSING	3	2	1	1

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Participants				
TSH > ULN	4			
TSH > ULN WITH TSH <= ULN AT BASELINE	2			
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0			
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	3			
TSH > ULN WITH FT3/FT4 TEST MISSING	1			
TSH < LLN	1			
TSH <LLN WITH TSH >= LLN AT BASELINE	1			
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0			
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0			
TSH < LLN WITH FT3/FT4 TEST MISSING	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Hepatic Test Results - Track 1

End point title	Number of Participants with Abnormal Hepatic Test Results - Track 1

End point description:

The number of participants with laboratory abnormalities in specific liver tests based on SI conventional units. ALT = Alanine Aminotransferase AST = Aspartate Aminotransferase ULN = Upper Limit of Normal. 99999= Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 30 days after last dose of study therapy (approximately 108 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	28	30	0[8]	0[9]
Units: Participants				
ALT OR AST > 3XULN	2	4		
ALT OR AST> 5XULN	1	2		
ALT OR AST> 10XULN	0	0		
ALT OR AST > 20XULN	0	0		
TOTAL BILIRUBIN > 2XULN	0	0		
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0	0		
ALT/AST ELEV>3XULN;TOT BILIRUBIN>2XULN IN 30 DAYS	0	0		

Notes:

[8] - No Track 1

[9] - No Track 1

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	0[10]			
Units: Participants				
ALT OR AST > 3XULN				
ALT OR AST> 5XULN				
ALT OR AST> 10XULN				
ALT OR AST > 20XULN				
TOTAL BILIRUBIN > 2XULN				
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY				
ALT/AST ELEV>3XULN;TOT BILIRUBIN>2XULN IN 30 DAYS				

Notes:

[10] - No Track 1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Abnormal Hepatic Test Results - Track 2

End point title	Number of Participants with Abnormal Hepatic Test Results - Track 2

End point description:

The number of participants with laboratory abnormalities in specific liver tests based on SI conventional units. ALT = Alanine Aminotransferase AST = Aspartate Aminotransferase ULN = Upper Limit of Normal. 99999 = Not Applicable/Available

End point type	Secondary

End point timeframe:

From first dose to 30 days after last dose of study therapy (approximately 108 weeks)

End point values	Arm 1: Nivolumab plus Ipilimumab (BMS-734016) (Experimental)	Arm 2: Nivolumab plus Relatlimab (BMS-986016) (Experimental)	Arm 3: Nivolumab plus BMS-986205 (Experimental)	Arm 4: Nivolumab plus BMS-813160 150 mg (Experimental)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	44	32	29	17
Units: Participants				
ALT OR AST > 3XULN	3	1	1	0
ALT OR AST> 5XULN	2	0	1	0
ALT OR AST> 10XULN	0	0	0	0
ALT OR AST > 20XULN	0	0	0	0
TOTAL BILIRUBIN > 2XULN	2	0	0	0
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0	0	0	0
ALT/AST ELEV>3XULN;TOT BILIRUBIN>2XULN IN 30 DAYS	0	0	0	0

End point values	Arm 5: Nivolumab plus BMS-813160 300mg (Experimental)			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Participants				
ALT OR AST > 3XULN	0			
ALT OR AST> 5XULN	0			
ALT OR AST> 10XULN	0			
ALT OR AST > 20XULN	0			
TOTAL BILIRUBIN > 2XULN	0			
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0			
ALT/AST ELEV>3XULN;TOT BILIRUBIN>2XULN IN 30 DAYS	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-Cause Mortality was assessed from first dose until study completion (up to approximately 258 weeks).
SAEs and NSAEs were assessed from first dose to 100 days after last dose of study therapy (assessed up to approximately 118 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Track 1 NIV+IPI
Reporting group description: -	
Reporting group title	Track 1 NIV+BMS986016
Reporting group description: -	
Reporting group title	Track 2 NIV+IPI
Reporting group description: -	
Reporting group title	Track 2 NIV+BMS986016
Reporting group description: -	
Reporting group title	Track 2 NIV+BMS986205
Reporting group description: -	
Reporting group title	Track 2 NIV+BMS813160 150MG QD
Reporting group description: -	
Reporting group title	Track 2 NIV+BMS813160 300MG BID

Reporting group description: -

Serious adverse events	Track 1 NIV+IPI	Track 1 NIV+BMS986016	Track 2 NIV+IPI
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 30 (56.67%)	15 / 30 (50.00%)	28 / 46 (60.87%)
number of deaths (all causes)	13	15	28
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Cancer pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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

Malignant neoplasm progression			
subjects affected / exposed	2 / 30 (6.67%)	5 / 30 (16.67%)	6 / 46 (13.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 3
Metastases to bone			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Metastases to central nervous system			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Tumour pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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

Embolism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Haematoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Lymphoedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Atelectasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Cough			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Pneumonitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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

Pneumothorax			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Pulmonary embolism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Respiratory arrest			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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 creatinine increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Lipase increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Fall			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Post procedural haematuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Wound dehiscence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac arrest			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac failure congestive			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Pericarditis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Encephalopathy			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Facial paralysis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated neuropathy			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Pyramidal tract syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Abdominal pain lower			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Enteritis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Large intestinal obstruction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Lip swelling			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Mouth haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Nausea			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Oesophagitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Vomiting			

subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Intertrigo			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (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
Rash			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Bladder perforation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune-mediated nephritis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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 haematoma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adrenal insufficiency			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myositis			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Groin pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Musculoskeletal chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Polymyalgia rheumatica			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Pneumonia			
subjects affected / exposed	4 / 30 (13.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (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
Urosepsis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Hypercalcaemia			

subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	2 / 46 (4.35%)
occurrences causally related to treatment / all	1 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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
Hypocalcaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (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	Track 2 NIV+BMS986016	Track 2 NIV+BMS986205	Track 2 NIV+BMS813160 150MG QD
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 32 (50.00%)	16 / 31 (51.61%)	9 / 21 (42.86%)
number of deaths (all causes)	17	13	10
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Cancer pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			

subjects affected / exposed	5 / 32 (15.63%)	3 / 31 (9.68%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 1
Metastases to bone			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Metastases to lung			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Prostate cancer			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Tumour pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Embolism			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Hypotension			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Lymphoedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Atelectasis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Cough			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Pulmonary embolism			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Investigations			
Amylase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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 alkaline phosphatase increased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Blood creatinine increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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 potassium increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Lipase increased			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Transaminases increased			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Fall			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Fracture			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Post procedural haematuria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Wound dehiscence			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Atrial fibrillation			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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

Cardiac arrest			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Brain oedema			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Dizziness			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Encephalopathy			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Facial paralysis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated neuropathy			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Neuralgia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Pyramidal tract syndrome			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Seizure			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Spinal cord compression			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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			

Abdominal pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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 lower			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Colitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Enterocolitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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 haemorrhage			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Lip swelling			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Mouth haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Oesophagitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Small intestinal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Cholecystitis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Hepatotoxicity			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Skin and subcutaneous tissue disorders			
Intertrigo			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Rash			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder perforation			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune-mediated nephritis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Oliguria			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haematoma			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adrenal insufficiency			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Autoimmune myositis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Back pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Flank pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Groin pain			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Muscular weakness			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Pain in extremity			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			

subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Epididymitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 32 (9.38%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Sialoadenitis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Sinusitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Urinary tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Urosepsis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Wound infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (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
Failure to thrive			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (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
Hyperkalaemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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
Hypocalcaemia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (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

Serious adverse events	Track 2 NIV+BMS813160 300MG BID		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 22 (68.18%)		
number of deaths (all causes)	13		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			

subjects affected / exposed	4 / 22 (18.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Metastases to bone				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to lung				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic renal cell carcinoma				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoedema				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Non-cardiac chest pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				

subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Amylase increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood potassium increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematuria			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cardiac arrest				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocarditis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericarditis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Aphasia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial paralysis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated neuropathy				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyramidal tract syndrome				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				

Abdominal pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain lower				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip swelling				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mouth haemorrhage				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal haemorrhage				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatotoxicity			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Intertrigo			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder perforation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Immune-mediated nephritis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oliguria				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal haematoma				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Adrenal insufficiency				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated adrenal insufficiency				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inappropriate antidiuretic hormone secretion				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune myositis				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epididymitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 22 (9.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sialoadenitis				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 22 (4.55%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypocalcaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Track 1 NIV+IPI	Track 1 NIV+BMS986016	Track 2 NIV+IPI
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 30 (93.33%)	29 / 30 (96.67%)	42 / 46 (91.30%)
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	1	2	1
Hypertension			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	4 / 46 (8.70%)
occurrences (all)	1	3	4
Hypotension			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	2	1	3
General disorders and administration site conditions			
Chest discomfort			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	3 / 46 (6.52%)
occurrences (all)	2	0	3
Fatigue			
subjects affected / exposed	9 / 30 (30.00%)	13 / 30 (43.33%)	15 / 46 (32.61%)
occurrences (all)	12	16	16
Chills			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	4 / 46 (8.70%)
occurrences (all)	3	2	5
Gait disturbance			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Non-cardiac chest pain			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences (all)	3	1	1
Mucosal inflammation			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	4 / 30 (13.33%)	3 / 30 (10.00%)	6 / 46 (13.04%)
occurrences (all)	5	3	7
Pyrexia			
subjects affected / exposed	5 / 30 (16.67%)	2 / 30 (6.67%)	5 / 46 (10.87%)
occurrences (all)	5	2	5
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 30 (36.67%)	6 / 30 (20.00%)	10 / 46 (21.74%)
occurrences (all)	12	6	10
Dysphonia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	3 / 46 (6.52%)
occurrences (all)	2	0	3
Dyspnoea			

subjects affected / exposed	7 / 30 (23.33%)	4 / 30 (13.33%)	6 / 46 (13.04%)
occurrences (all)	7	4	6
Dyspnoea exertional			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Epistaxis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	1	0	2
Nasal congestion			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences (all)	3	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 30 (3.33%)	4 / 30 (13.33%)	1 / 46 (2.17%)
occurrences (all)	1	5	1
Pleuritic pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Pleural effusion			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Pneumothorax			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	0	2	1
Pneumonitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 30 (0.00%)	4 / 30 (13.33%)	0 / 46 (0.00%)
occurrences (all)	0	4	0
Rhinorrhoea			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	1 / 46 (2.17%)
occurrences (all)	1	3	1

Depression			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	0 / 46 (0.00%)
occurrences (all)	1	2	0
Insomnia			
subjects affected / exposed	5 / 30 (16.67%)	2 / 30 (6.67%)	4 / 46 (8.70%)
occurrences (all)	5	2	4
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	5 / 46 (10.87%)
occurrences (all)	1	4	7
Amylase increased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	3 / 46 (6.52%)
occurrences (all)	2	0	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	5 / 46 (10.87%)
occurrences (all)	1	1	7
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	0 / 46 (0.00%)
occurrences (all)	1	3	0
Blood creatinine increased			
subjects affected / exposed	5 / 30 (16.67%)	3 / 30 (10.00%)	2 / 46 (4.35%)
occurrences (all)	6	3	3
Blood bilirubin increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Lipase increased			
subjects affected / exposed	4 / 30 (13.33%)	1 / 30 (3.33%)	3 / 46 (6.52%)
occurrences (all)	5	1	6
Weight decreased			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	5 / 46 (10.87%)
occurrences (all)	3	1	6
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)	2 / 46 (4.35%)
occurrences (all)	0	3	2
Fall			

subjects affected / exposed	1 / 30 (3.33%)	4 / 30 (13.33%)	5 / 46 (10.87%)
occurrences (all)	1	4	6
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Dizziness			
subjects affected / exposed	5 / 30 (16.67%)	3 / 30 (10.00%)	6 / 46 (13.04%)
occurrences (all)	6	4	6
Dizziness postural			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	1 / 46 (2.17%)
occurrences (all)	1	3	1
Lethargy			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	4 / 30 (13.33%)	10 / 30 (33.33%)	5 / 46 (10.87%)
occurrences (all)	5	15	7
Paraesthesia			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	1 / 46 (2.17%)
occurrences (all)	1	3	1
Spinal cord compression			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 46 (0.00%)
occurrences (all)	0	2	0
Taste disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Tremor			

subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 30 (26.67%)	5 / 30 (16.67%)	8 / 46 (17.39%)
occurrences (all)	8	6	9
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	0	2	1
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	0 / 46 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	5 / 46 (10.87%)
occurrences (all)	4	1	5
Colitis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	6 / 30 (20.00%)	9 / 30 (30.00%)	14 / 46 (30.43%)
occurrences (all)	14	14	18
Constipation			
subjects affected / exposed	3 / 30 (10.00%)	8 / 30 (26.67%)	5 / 46 (10.87%)
occurrences (all)	3	8	5
Dry mouth			
subjects affected / exposed	1 / 30 (3.33%)	4 / 30 (13.33%)	4 / 46 (8.70%)
occurrences (all)	1	4	4
Epigastric discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Nausea			
subjects affected / exposed	10 / 30 (33.33%)	7 / 30 (23.33%)	14 / 46 (30.43%)
occurrences (all)	12	11	16
Oral pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	0	0	2
Stomatitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	6 / 46 (13.04%)
occurrences (all)	0	0	6
Vomiting			
subjects affected / exposed	5 / 30 (16.67%)	6 / 30 (20.00%)	7 / 46 (15.22%)
occurrences (all)	11	6	10
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Dry skin			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	2	1	2
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	0	1	2
Night sweats			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	3	1	0
Rash			
subjects affected / exposed	8 / 30 (26.67%)	7 / 30 (23.33%)	12 / 46 (26.09%)
occurrences (all)	10	7	14
Pruritus			
subjects affected / exposed	10 / 30 (33.33%)	6 / 30 (20.00%)	10 / 46 (21.74%)
occurrences (all)	10	7	11
Rash maculo-papular			

subjects affected / exposed	5 / 30 (16.67%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	5	2	3
Rash pruritic			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Rosacea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	3	0	0
Dysuria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Pollakiuria			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	2 / 46 (4.35%)
occurrences (all)	2	0	2
Urinary retention			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	2	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	4 / 30 (13.33%)	3 / 30 (10.00%)	0 / 46 (0.00%)
occurrences (all)	4	3	0
Hypothyroidism			
subjects affected / exposed	4 / 30 (13.33%)	6 / 30 (20.00%)	2 / 46 (4.35%)
occurrences (all)	4	6	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 30 (20.00%)	1 / 30 (3.33%)	5 / 46 (10.87%)
occurrences (all)	7	2	5
Flank pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences (all)	2	0	1
Back pain			

subjects affected / exposed	3 / 30 (10.00%)	5 / 30 (16.67%)	6 / 46 (13.04%)
occurrences (all)	5	6	7
Groin pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 46 (2.17%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	6 / 46 (13.04%)
occurrences (all)	4	2	7
Muscle spasms			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Myalgia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	2	2	1
Neck pain			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	2	1	2
Pain in extremity			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	0 / 46 (0.00%)
occurrences (all)	3	3	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	3 / 46 (6.52%)
occurrences (all)	1	1	3
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences (all)	0	1	1
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	1	1	0

Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	4 / 46 (8.70%)
occurrences (all)	1	0	4
Upper respiratory tract infection			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	5 / 46 (10.87%)
occurrences (all)	3	3	5
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 30 (16.67%)	5 / 30 (16.67%)	12 / 46 (26.09%)
occurrences (all)	7	5	13
Hypercalcaemia			
subjects affected / exposed	4 / 30 (13.33%)	2 / 30 (6.67%)	3 / 46 (6.52%)
occurrences (all)	4	2	3
Hyperglycaemia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	2 / 46 (4.35%)
occurrences (all)	3	1	2
Hyperkalaemia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	3 / 46 (6.52%)
occurrences (all)	1	1	4
Hypoalbuminaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	1 / 46 (2.17%)
occurrences (all)	2	1	1
Hypokalaemia			
subjects affected / exposed	4 / 30 (13.33%)	0 / 30 (0.00%)	0 / 46 (0.00%)
occurrences (all)	5	0	0
Hypomagnesaemia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	0 / 46 (0.00%)
occurrences (all)	2	1	0
Hyponatraemia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	1	2	5
Hypophosphataemia			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	1 / 46 (2.17%)
occurrences (all)	2	2	1

Non-serious adverse events	Track 2 NIV+BMS986016	Track 2 NIV+BMS986205	Track 2 NIV+BMS813160 150MG QD

Total subjects affected by non-serious adverse events subjects affected / exposed	31 / 32 (96.88%)	29 / 31 (93.55%)	18 / 21 (85.71%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	2 / 21 (9.52%)
occurrences (all)	1	1	2
Hypotension			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	3
Asthenia			
subjects affected / exposed	2 / 32 (6.25%)	3 / 31 (9.68%)	2 / 21 (9.52%)
occurrences (all)	3	3	2
Fatigue			
subjects affected / exposed	11 / 32 (34.38%)	8 / 31 (25.81%)	7 / 21 (33.33%)
occurrences (all)	13	8	7
Chills			
subjects affected / exposed	3 / 32 (9.38%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Gait disturbance			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 32 (9.38%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Mucosal inflammation			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	3
Oedema peripheral			

subjects affected / exposed	4 / 32 (12.50%)	6 / 31 (19.35%)	1 / 21 (4.76%)
occurrences (all)	4	6	1
Pyrexia			
subjects affected / exposed	5 / 32 (15.63%)	2 / 31 (6.45%)	1 / 21 (4.76%)
occurrences (all)	5	2	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 32 (25.00%)	6 / 31 (19.35%)	6 / 21 (28.57%)
occurrences (all)	9	6	6
Dysphonia			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	3 / 32 (9.38%)	7 / 31 (22.58%)	2 / 21 (9.52%)
occurrences (all)	3	7	2
Dyspnoea exertional			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Epistaxis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Nasal congestion			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 32 (0.00%)	3 / 31 (9.68%)	1 / 21 (4.76%)
occurrences (all)	0	5	1
Pneumothorax			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Productive cough			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	3 / 21 (14.29%)
occurrences (all)	1	1	3
Rhinorrhoea			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	2 / 21 (9.52%)
occurrences (all)	1	1	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	2 / 21 (9.52%)
occurrences (all)	1	2	3
Amylase increased			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 32 (6.25%)	3 / 31 (9.68%)	3 / 21 (14.29%)
occurrences (all)	2	3	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Blood creatinine increased			

subjects affected / exposed	0 / 32 (0.00%)	3 / 31 (9.68%)	2 / 21 (9.52%)
occurrences (all)	0	4	10
Blood bilirubin increased			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Weight decreased			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	2	1	1
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	5	2	1
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Dizziness			
subjects affected / exposed	4 / 32 (12.50%)	2 / 31 (6.45%)	3 / 21 (14.29%)
occurrences (all)	5	2	3
Dizziness postural			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Lethargy			

subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Headache			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	3 / 21 (14.29%)
occurrences (all)	1	2	3
Paraesthesia			
subjects affected / exposed	4 / 32 (12.50%)	1 / 31 (3.23%)	2 / 21 (9.52%)
occurrences (all)	4	1	2
Spinal cord compression			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 32 (0.00%)	3 / 31 (9.68%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
Tremor			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 32 (12.50%)	4 / 31 (12.90%)	2 / 21 (9.52%)
occurrences (all)	4	4	2
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	3 / 32 (9.38%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	3	0	0
Vision blurred			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 32 (12.50%)	2 / 31 (6.45%)	1 / 21 (4.76%)
occurrences (all)	4	2	1
Colitis			

subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	7 / 32 (21.88%)	5 / 31 (16.13%)	6 / 21 (28.57%)
occurrences (all)	7	5	7
Constipation			
subjects affected / exposed	12 / 32 (37.50%)	6 / 31 (19.35%)	2 / 21 (9.52%)
occurrences (all)	12	6	2
Dry mouth			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 32 (3.13%)	2 / 31 (6.45%)	1 / 21 (4.76%)
occurrences (all)	1	2	1
Nausea			
subjects affected / exposed	8 / 32 (25.00%)	8 / 31 (25.81%)	6 / 21 (28.57%)
occurrences (all)	8	9	6
Oral pain			
subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	2	0	2
Stomatitis			
subjects affected / exposed	3 / 32 (9.38%)	1 / 31 (3.23%)	4 / 21 (19.05%)
occurrences (all)	3	2	4
Vomiting			
subjects affected / exposed	2 / 32 (6.25%)	6 / 31 (19.35%)	2 / 21 (9.52%)
occurrences (all)	3	7	3
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	2 / 32 (6.25%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	2	2	0

Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
Night sweats			
subjects affected / exposed	3 / 32 (9.38%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	3	1	1
Rash			
subjects affected / exposed	7 / 32 (21.88%)	3 / 31 (9.68%)	4 / 21 (19.05%)
occurrences (all)	8	3	5
Pruritus			
subjects affected / exposed	8 / 32 (25.00%)	2 / 31 (6.45%)	3 / 21 (14.29%)
occurrences (all)	9	2	4
Rash maculo-papular			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Dysuria			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Urinary retention			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Endocrine disorders			

Hyperthyroidism			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 32 (0.00%)	3 / 31 (9.68%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 32 (21.88%)	7 / 31 (22.58%)	2 / 21 (9.52%)
occurrences (all)	8	9	2
Flank pain			
subjects affected / exposed	4 / 32 (12.50%)	2 / 31 (6.45%)	1 / 21 (4.76%)
occurrences (all)	4	2	1
Back pain			
subjects affected / exposed	7 / 32 (21.88%)	6 / 31 (19.35%)	3 / 21 (14.29%)
occurrences (all)	7	6	3
Groin pain			
subjects affected / exposed	0 / 32 (0.00%)	2 / 31 (6.45%)	2 / 21 (9.52%)
occurrences (all)	0	2	2
Muscular weakness			
subjects affected / exposed	2 / 32 (6.25%)	3 / 31 (9.68%)	2 / 21 (9.52%)
occurrences (all)	2	3	2
Muscle spasms			
subjects affected / exposed	1 / 32 (3.13%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
Myalgia			
subjects affected / exposed	5 / 32 (15.63%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	6	0	0
Neck pain			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	5 / 32 (15.63%)	4 / 31 (12.90%)	1 / 21 (4.76%)
occurrences (all)	5	4	1
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 31 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
Conjunctivitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	3 / 32 (9.38%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	4	0	0
Influenza			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	2	1	1
Pneumonia			
subjects affected / exposed	3 / 32 (9.38%)	0 / 31 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Urinary tract infection			
subjects affected / exposed	0 / 32 (0.00%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 32 (12.50%)	3 / 31 (9.68%)	2 / 21 (9.52%)
occurrences (all)	5	3	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	8 / 32 (25.00%)	4 / 31 (12.90%)	5 / 21 (23.81%)
occurrences (all)	8	4	5
Hypercalcaemia			
subjects affected / exposed	3 / 32 (9.38%)	1 / 31 (3.23%)	2 / 21 (9.52%)
occurrences (all)	3	1	3
Hyperglycaemia			
subjects affected / exposed	1 / 32 (3.13%)	3 / 31 (9.68%)	0 / 21 (0.00%)
occurrences (all)	1	3	0
Hyperkalaemia			
subjects affected / exposed	2 / 32 (6.25%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	2	1	0
Hypoalbuminaemia			

subjects affected / exposed	2 / 32 (6.25%)	0 / 31 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Hyponatraemia			
subjects affected / exposed	2 / 32 (6.25%)	2 / 31 (6.45%)	0 / 21 (0.00%)
occurrences (all)	4	2	0
Hypophosphataemia			
subjects affected / exposed	1 / 32 (3.13%)	1 / 31 (3.23%)	2 / 21 (9.52%)
occurrences (all)	1	1	2

Non-serious adverse events	Track 2 NIV+BMS813160 300MG BID		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 22 (77.27%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Fatigue			

subjects affected / exposed	6 / 22 (27.27%)		
occurrences (all)	6		
Chills			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Dysphonia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Dyspnoea exertional			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Epistaxis			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Pleuritic pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pneumothorax			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Pneumonitis			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Amylase increased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Blood bilirubin increased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Dizziness postural			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Paraesthesia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Spinal cord compression			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Colitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Dry mouth			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Epigastric discomfort			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Oral pain			

subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Rash pruritic			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Rosacea			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hypothyroidism			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Flank pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	4 / 22 (18.18%)		
occurrences (all)	4		
Groin pain			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Muscular weakness			

subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 22 (9.09%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 22 (13.64%)		
occurrences (all)	3		
Hypercalcaemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hyperkalaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 September 2016	Clarification of the overall study design
01 March 2017	Removal of Legally Authorized Representative language, Clarification of Inclusion Criteria, updates to the procedural outline
15 June 2017	Change of Study Director/Medical Monitor, Restoration of inadvertently deleted neutrophil inclusion criterion and clarification of hemoglobin inclusion criterion
23 November 2021	Given the rapidly evolving treatment landscape in renal cell carcinoma (RCC), having only 1 patient left on safety follow-up, and the complexity and operational challenges faced, the FRACTION-RCC study is planned for closure once the last patient finishes the safety follow-up. The planned termination of the FRACTION-RCC study is not due to any safety concerns. Due to planned early closure of the trial, the study schedule was adjusted to remove retreatment/re-randomization options, response follow-up, and survival follow-up periods for all parts of the study. No changes were made to the treatment period or safety follow-up period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported