Clinical trial results:
A Phase 2 Randomized Study of BMS-986207 in Combination with Nivolumab and Ipilimumab as First-line Treatment for Participants with Stage IV Non-Small Cell Lung Cancer

Summary

EudraCT number	2021-000039-29
Trial protocol	BE DE ES PL
Global end of trial date	27 December 2022

Results information

Result version number	v1 (current)
This version publication date	31 December 2023
First version publication date	31 December 2023

Trial information

Trial identification

Sponsor protocol code	CA020-016

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05005273
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 December 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the PFS of BMS-986207 in combination with nivolumab plus ipilimumab versus nivolumab plus ipilimumab.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 September 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	1
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1 participant randomized and treated in arm 1. No enrollment in Arm 2 (nivolumab 360mg Q3W Ipilimumab 1mg/kg Q6W Placebo Q3W).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Arm title	Treatment 1

Arm description:

nivolumab 360mg Q3W Ipilimumab 1mg/kg Q6W BMS-986207 600mg Q3W

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

Dosage and administration details:

360mg Q3W

Investigational medicinal product name	BMS-986207
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

600mg Q3W

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

Dosage and administration details:

1mg/kg Q6W

Number of subjects in period 1	Treatment 1
Started	1
Completed	0
Not completed	1
Study Terminated	1

Baseline characteristics

Reporting groups	
Reporting group title	Treatment 1
Reporting group description: nivolumab 360mg Q3W Ipilimumab 1mg/kg Q6W BMS-986207 600mg Q3W	

Reporting group values	Treatment 1	Total	
Number of subjects	1	1	
Age Categorical Units: Participants			
<=18 years	0	0	
Between 18 and 65 years	0	0	
>=65 years	1	1	
Age continuous Units: years			
arithmetic mean	65		
full range (min-max)	65 to 65	-	
Sex: Female, Male Units: Participants			
Female	1	1	
Male	0	0	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	1	1	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	1	1	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Treatment 1
Reporting group description: nivolumab 360mg Q3W Ipilimumab 1mg/kg Q6W BMS-986207 600mg Q3W	

Primary: Progression Free Survival by BICR

End point title	Progression Free Survival by BICR[1]

End point description:

PFS is defined for all randomized participants as the date from randomization to the date of the documentation of disease progression by BICR or death due to any cause, whichever is earlier.

Progressive Disease (PD): 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. The appearance of one or more new lesions is also considered progression.

here "99999" means NA

End point type	Primary

End point timeframe:

From first dose to progression or death, 2.3 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Not enough subjects for statistical analysis

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1[2]			
Units: Months				
arithmetic mean (confidence interval 95%)	99999 (99999 to 99999)			

Notes:

[2] - no subjects with BICR analysis

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) by BICR

End point title	Overall Response Rate (ORR) by BICR

End point description:

ORR is defined as the percentage of participants with a confirmed Best overall response of Complete Response (CR) or Partial Response (PR) by RECIST v1.1.

Complete Response (CR): 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): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose to progression or death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1[3]			
Units: Months				
arithmetic mean (confidence interval 95%)	99999 (99999 to 99999)			

Notes:

[3] - no subjects with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) by Investigator

End point title	Duration of Response (DOR) by Investigator

End point description:

DOR is defined for participants who have a confirmed CR or PR as the date from first documented CR or PR per RECIST v1.1 to the date of the documentation of disease progression or death due to any cause, whichever is earlier.

Complete Response (CR): 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): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose to progression or death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1[4]			
Units: Months				
arithmetic mean (confidence interval 95%)	99999 (99999 to 99999)			

Notes:

[4] - no subjects with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who had AEs, SAEs, AEs Leading to discontinuation and Deaths.

End point title	Number of participants who had AEs, SAEs, AEs Leading to discontinuation and Deaths.

End point description:

End point type	Secondary

End point timeframe:

From first dose to progression or death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Participants				
Adverse Events	0			
Serious Adverse Events	1			
AEs leading to discontinuation	0			
Deaths	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS is defined as the time from randomization to the time of death due to any cause.

Here "99999" means NA

End point type	Secondary

End point timeframe:

From randomization to time of death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Months				
arithmetic mean (confidence interval 95%)	2.3 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) by Investigator

End point title	Overall Response Rate (ORR) by Investigator

End point description:

ORR is defined as the percentage of participants with a confirmed Best overall response of Complete Response (CR) or Partial Response (PR) by RECIST v1.1.

Complete Response (CR): 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): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose to progression or death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	0[5]			
Units: Months				
arithmetic mean (confidence interval 95%)	(to)			

Notes:

[5] - No subjects with CR or PR

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival by Investigator

End point title	Progression Free Survival by Investigator

End point description:

PFS is defined for all randomized participants as the date from randomization to the date of the documentation of disease progression by BICR or death due to any cause, whichever is earlier.

Progressive Disease (PD): 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. The appearance of one or more new lesions is also considered progression.

here "99999" means NA

End point type	Secondary

End point timeframe:

From first dose to progression or death, 2.3 months

End point values	Treatment 1			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Months				
arithmetic mean (confidence interval 95%)	2.3 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events and Serious Adverse Events (From first dose to last dose + 100 days) and All-Cause mortality (From randomization to end of study): 2.3 Months

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	MedDRA25.1

Reporting groups

Reporting group title	Nivolumab 360 mg + Ipilimumab 1 mg/kg + BMS-986207 600 mg

Reporting group description: -

Serious adverse events	Nivolumab 360 mg + Ipilimumab 1 mg/kg + BMS-986207 600 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Infections and infestations			
Sepsis			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	Nivolumab 360 mg + Ipilimumab 1 mg/kg + BMS-986207 600 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Hypoalbuminaemia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 June 2022	The study design has been updated from double-blind randomized assignment to single-blind randomized assignment. Investigators, site staff, and participants will be blinded to BMS-986207 treatment assignment. Data Monitoring Committee (DMC) and Sponsor will be unblinded to treatment assignment to monitor safety

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported