Clinical trial results:
A Phase 1/2, Open-Label, Dose-Escalation/Dose-Expansion, Safety and Tolerability Study of INCB059872 in Subjects With Advanced Malignancies

Summary

EudraCT number	2017-001710-28
Trial protocol	BE
Global end of trial date	14 April 2022

Results information

Result version number	v1
This version publication date	26 April 2023
First version publication date	26 April 2023

Trial information

Trial identification

Sponsor protocol code	INCB 59872-101

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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	14 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 April 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Part 1: To evaluate the safety and tolerability and determine the recommended dose(s) of INCB059872 for further study in advanced malignancies.

Part 2: To further evaluate the safety and tolerability of INCB059872 for further study in advanced malignancies.

Part 3: To evaluate the safety and tolerability and determine the recommended dose of INCB059872 in combination with other therapies for further study in advanced malignancies.

Part 4: To further evaluate the safety and tolerability of INCB059872 in combination with other therapies in advanced malignancies.

Protection of trial subjects:

This study was to have been performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, Good Clinical Practices as defined in Title 21 of the United States Code of Federal Regulations Parts 11, 50, 54, 56, and 312, as well as International Council for Harmonization Good Clinical Practice consolidated guidelines (E6) and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 104
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Netherlands: 2
Worldwide total number of subjects	115
EEA total number of subjects	11

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	62
From 65 to 84 years	53
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled at 12 study sites: 10 in the United States and 1 each in Belgium and the Netherlands.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group A: INCB059872 Monotherapy; 2 mg QOD

Arm description:

Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group A: INCB059872 Monotherapy; 2 mg QD

Arm description:

Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group A: INCB059872 Monotherapy; 3 mg QOD

Arm description:

Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Arm type	Experimental

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group A: INCB059872 Monotherapy; 3 mg QD

Arm description:

Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group A: INCB059872 Monotherapy; 4 mg QD

Arm description:

Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group A: INCB059872 Monotherapy; 5 mg QD

Arm description:

Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 1 mg QD

Arm description:

Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 2 mg QOD

Arm description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 2 mg QD

Arm description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 3 mg QOD

Arm description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 3 mg QD

Arm description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

Arm type	Experimental

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group B: INCB059872 Monotherapy; 4 mg QOD

Arm description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA

Arm description:

Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all-trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m^2] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Investigational medicinal product name	ATRA
Investigational medicinal product code	
Other name	tretinoin
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

10 mg concentration

Arm title	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA

Arm description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	ATRA
Investigational medicinal product code	
Other name	tretinoin
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

10 mg concentration

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA

Arm description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Arm type	Experimental
Investigational medicinal product name	ATRA
Investigational medicinal product code	
Other name	tretinoin
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

10 mg concentration

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine

Arm description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

25 mg/milliliter (mL) concentration

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine

Arm description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75

mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	Azacitidine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

25 mg/milliliter (mL) concentration

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Arm title	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab

Arm description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

10 mg/mL concentration

Investigational medicinal product name	INCB059872
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1 mg concentration

Number of subjects in period 1	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD
Started	3	6	1
Completed	0	0	0
Not completed	3	6	1
Adverse event, serious fatal	2	5	-
Physician decision	1	-	-
Consent withdrawn by subject	-	-	1

Unknown; No EOS Form Prior to Site Closure	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated by Sponsor	-	-	-
Started New Cancer Drug	-	-	-
Lost to follow-up	-	1	-

Number of subjects in period 1	Group A: INCB059872 Monotherapy; 3 mg QD	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD
Started	5	18	2
Completed	0	0	0
Not completed	5	18	2
Adverse event, serious fatal	3	15	1
Physician decision	1	-	-
Consent withdrawn by subject	-	2	-
Unknown; No EOS Form Prior to Site Closure	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated by Sponsor	-	1	-
Started New Cancer Drug	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD	Group B: INCB059872 Monotherapy; 2 mg QD
Started	3	3	1
Completed	0	0	0
Not completed	3	3	1
Adverse event, serious fatal	3	3	-
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Unknown; No EOS Form Prior to Site Closure	-	-	-
Adverse event, non-fatal	-	-	1
Study Terminated by Sponsor	-	-	-
Started New Cancer Drug	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Started	36	3	7
Completed	0	0	0
Not completed	36	3	7
Adverse event, serious fatal	27	2	5

Physician decision	1	-	-
Consent withdrawn by subject	4	1	2
Unknown; No EOS Form Prior to Site Closure	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated by Sponsor	2	-	-
Started New Cancer Drug	-	-	-
Lost to follow-up	2	-	-

Number of subjects in period 1	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA
Started	5	7	1
Completed	0	0	0
Not completed	5	7	1
Adverse event, serious fatal	5	6	1
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Unknown; No EOS Form Prior to Site Closure	-	-	-
Adverse event, non-fatal	-	-	-
Study Terminated by Sponsor	-	1	-
Started New Cancer Drug	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab
Started	7	1	6
Completed	0	0	0
Not completed	7	1	6
Adverse event, serious fatal	3	1	3
Physician decision	-	-	-
Consent withdrawn by subject	1	-	2
Unknown; No EOS Form Prior to Site Closure	1	-	-
Adverse event, non-fatal	-	-	-
Study Terminated by Sponsor	2	-	1
Started New Cancer Drug	-	-	-
Lost to follow-up	-	-	-

Reporting groups

Reporting group title	Group A: INCB059872 Monotherapy; 2 mg QOD

Reporting group description:

Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle.

Reporting group title	Group A: INCB059872 Monotherapy; 2 mg QD

Reporting group description:

Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.

Reporting group title	Group A: INCB059872 Monotherapy; 3 mg QOD

Reporting group description:

Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Reporting group title	Group A: INCB059872 Monotherapy; 3 mg QD

Reporting group description:

Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group A: INCB059872 Monotherapy; 4 mg QD

Reporting group description:

Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group A: INCB059872 Monotherapy; 5 mg QD

Reporting group description:

Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 1 mg QD

Reporting group description:

Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 2 mg QOD

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 2 mg QD

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 3 mg QOD

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 3 mg QD

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; 4 mg QOD

Reporting group description:

Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all-

trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m^2] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Reporting group title	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Reporting group title	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

Reporting group values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD
Number of subjects	3	6	1
Age categorical Units: Subjects			
Adults (18-64 years)	2	5	0
From 65-84 years	1	1	1
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years arithmetic mean standard deviation	 65.0 ± 5.20	 58.0 ± 9.53	 120 ± 120
Sex: Female, Male Units: participants			
Female	3	3	0
Male	0	3	0
Not Being Reported Due to Privacy Concerns	0	0	1
Race/Ethnicity, Customized Units: Subjects			
White	3	4	0

Black or African American	0	2	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Non-White	0	0	0
Unknown/Not Specified	0	0	0
Declined to Report	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	3	5	0
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	1

Reporting group values	Group A: INCB059872 Monotherapy; 3 mg QD	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD
Number of subjects	5	18	2
Age categorical			
Units: Subjects			
Adults (18-64 years)	2	8	2
From 65-84 years	3	10	0
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years			
arithmetic mean	57.4	63.8	51.0
standard deviation	± 21.93	± 12.02	± 18.38
Sex: Female, Male			
Units: participants			
Female	3	9	2
Male	2	9	0
Not Being Reported Due to Privacy Concerns	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
White	4	15	2
Black or African American	0	1	0
Asian	0	0	0
American-Indian/Alaska Native	0	1	0
Non-White	1	0	0
Unknown/Not Specified	0	1	0
Declined to Report	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	2	1
Not Hispanic or Latino	5	16	1
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	0

Reporting group values	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD	Group B: INCB059872 Monotherapy; 2 mg QD
Number of subjects	3	3	1
Age categorical Units: Subjects			
Adults (18-64 years)	2	1	1
From 65-84 years	1	2	0
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years arithmetic mean standard deviation	46.3 ± 22.59	63.0 ± 17.09	120 ± 120
Sex: Female, Male Units: participants			
Female	1	3	0
Male	2	0	0
Not Being Reported Due to Privacy Concerns	0	0	1
Race/Ethnicity, Customized Units: Subjects			
White	2	2	0
Black or African American	0	1	0
Asian	1	0	0
American-Indian/Alaska Native	0	0	0
Non-White	0	0	0
Unknown/Not Specified	0	0	0
Declined to Report	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	0
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	1

Reporting group values	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Number of subjects	36	3	7
Age categorical Units: Subjects			
Adults (18-64 years)	22	3	5
From 65-84 years	14	0	2
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years arithmetic mean standard deviation	57.8 ± 13.95	51.0 ± 11.53	63.0 ± 4.86

Sex: Female, Male Units: participants			
Female	16	0	4
Male	20	3	3
Not Being Reported Due to Privacy Concerns	0	0	0
Race/Ethnicity, Customized Units: Subjects			
White	31	3	6
Black or African American	3	0	1
Asian	1	0	0
American-Indian/Alaska Native	0	0	0
Non-White	0	0	0
Unknown/Not Specified	1	0	0
Declined to Report	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	36	3	7
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	0

Reporting group values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA
Number of subjects	5	7	1
Age categorical Units: Subjects			
Adults (18-64 years)	3	3	1
From 65-84 years	2	4	0
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years			
arithmetic mean	61.0	63.6	120
standard deviation	± 9.19	± 13.83	± 120
Sex: Female, Male Units: participants			
Female	0	4	0
Male	5	3	0
Not Being Reported Due to Privacy Concerns	0	0	1
Race/Ethnicity, Customized Units: Subjects			
White	5	6	0
Black or African American	0	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Non-White	0	0	0
Unknown/Not Specified	0	0	0

Declined to Report	0	1	0
Not Being Reported Due to Privacy Concerns	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	7	0
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	0	1

Reporting group values	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab
Number of subjects	7	1	6
Age categorical Units: Subjects			
Adults (18-64 years)	1	0	1
From 65-84 years	6	1	5
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years			
arithmetic mean	73.4	120	68.7
standard deviation	± 9.02	± 120	± 9.48
Sex: Female, Male Units: participants			
Female	3	0	3
Male	4	0	3
Not Being Reported Due to Privacy Concerns	0	1	0
Race/Ethnicity, Customized Units: Subjects			
White	7	0	6
Black or African American	0	0	0
Asian	0	0	0
American-Indian/Alaska Native	0	0	0
Non-White	0	0	0
Unknown/Not Specified	0	0	0
Declined to Report	0	0	0
Not Being Reported Due to Privacy Concerns	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	0	6
Unknown or Not Reported	0	0	0
Not Being Reported Due to Privacy Concerns	0	1	0

Reporting group values	Total		
Number of subjects	115		

Age categorical Units: Subjects			
Adults (18-64 years)	62		
From 65-84 years	53		
Age Continuous			
120=Unable to report age for a single participant due to privacy concerns.			
Units: years arithmetic mean standard deviation	- -		
Sex: Female, Male Units: participants			
Female	54		
Male	57		
Not Being Reported Due to Privacy Concerns	4		
Race/Ethnicity, Customized Units: Subjects			
White	96		
Black or African American	8		
Asian	2		
American-Indian/Alaska Native	1		
Non-White	1		
Unknown/Not Specified	2		
Declined to Report	1		
Not Being Reported Due to Privacy Concerns	4		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4		
Not Hispanic or Latino	107		
Unknown or Not Reported	0		
Not Being Reported Due to Privacy Concerns	4		

End points

End points reporting groups

Reporting group title	Group A: INCB059872 Monotherapy; 2 mg QOD
Reporting group description:	
Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) as monotherapy once every other day (QOD) on a 28-day continuous therapy cycle.	
Reporting group title	Group A: INCB059872 Monotherapy; 2 mg QD
Reporting group description:	
Participants with AML or MDS received oral INB059872 2 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.	
Reporting group title	Group A: INCB059872 Monotherapy; 3 mg QOD
Reporting group description:	
Participants with AML or MDS received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.	
Reporting group title	Group A: INCB059872 Monotherapy; 3 mg QD
Reporting group description:	
Participants with AML or MDS received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group A: INCB059872 Monotherapy; 4 mg QD
Reporting group description:	
Participants with AML or MDS received oral INB059872 4 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group A: INCB059872 Monotherapy; 5 mg QD
Reporting group description:	
Participants with AML or MDS received oral INB059872 5 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 1 mg QD
Reporting group description:	
Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 2 mg QOD
Reporting group description:	
Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QOD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 2 mg QD
Reporting group description:	
Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 2 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 3 mg QOD
Reporting group description:	
Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QOD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 3 mg QD
Reporting group description:	
Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 3 mg as monotherapy QD on a 28-day continuous therapy cycle.	
Reporting group title	Group B: INCB059872 Monotherapy; 4 mg QOD
Reporting group description:	
Participants with SCLC and other solid malignancies (e.g., endocrine tumors) received oral INB059872 4 mg as monotherapy QOD on a 28-day continuous therapy cycle.	
Reporting group title	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA
Reporting group description:	
Participants with relapsed/refractory AML received oral INCB059872 2 mg QD in combination with all-	

trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m^2] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 3 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 4 mg QD in combination with ATRA (at a starting dose of 45 mg/m^2 per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Reporting group title	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Reporting group title	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Reporting group title	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

Primary: Number of participants receiving INCB059872 monotherapy with any treatment-emergent adverse event (TEAE)

End point title	Number of participants receiving INCB059872 monotherapy with any treatment-emergent adverse event (TEAE)[1][2]

End point description:

Adverse events (AEs) were defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as AEs either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug.

End point type	Primary

End point timeframe:

up to 588 days

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not performed for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	1	5
Units: participants	3	6	1	5

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	2	3	3
Units: participants	18	2	3	3

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	36	3	7
Units: participants	1	36	3	7

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants receiving INCB059872 combination therapy with any TEAE

End point title	Number of participants receiving INCB059872 combination therapy with any TEAE[3][4]

End point description:

AEs were defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, that occurred after a participant provided informed consent. Abnormal laboratory values or test results occurring after informed consent constituted AEs only if they induced clinical signs or symptoms, were considered clinically meaningful, required therapy (e.g., hematologic abnormality that required transfusion), or required changes in the study drug(s). TEAEs were defined as AEs either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug.

End point type	Primary

End point timeframe:

up to 1387 days

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not performed for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	1	7
Units: participants	5	7	1	7

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	6		
Units: participants	1	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR) in participants with the indicated type of solid tumors who received INCB059872 monotherapy

End point title	Objective response rate (ORR) in participants with the indicated type of solid tumors who received INCB059872 monotherapy[5]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete response (CR) or a partial response (PR), per investigator assessment according to Response Evaluation Criteria in Solid Tumors version 1.1 (RESIST v1.1), recorded before and including the first event of progressive disease (PD). CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. 9999=participants in treatment group did not have indicated type of solid tumor and thus did not contribute to the analysis. PDNTs=poorly differentiated neuroendocrine tumors.

End point type	Secondary

End point timeframe:

up to 518 days

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[6]	0[7]	0[8]	0[9]
Units: percentage of participants				
number (not applicable)				
SCLC; Group B, n=0, 0, 0, 18, 1, 3				
Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0				
PDNTs; Group B, n=1, 0, 0, 12, 0, 0				
Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4				

Notes:

[6] - Participants did not have solid tumors and thus did not contribute to the analysis.

[7] - Participants did not have solid tumors and thus did not contribute to the analysis.

[8] - Participants did not have solid tumors and thus did not contribute to the analysis.

[9] - Participants did not have solid tumors and thus did not contribute to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[10]	0[11]	3[12]	3[13]
Units: percentage of participants				
number (not applicable)				
SCLC; Group B, n=0, 0, 0, 18, 1, 3			9999	9999
Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0			9999	9999
PDNTs; Group B, n=1, 0, 0, 12, 0, 0			0.0	9999
Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4			0.0	0.0

Notes:

[10] - Participants did not have solid tumors and thus did not contribute to the analysis.

[11] - Participants did not have solid tumors and thus did not contribute to the analysis.

[12] - Only participants with the indicated type of solid tumor contributed to the analysis.

[13] - Only participants with the indicated type of solid tumor contributed to the analysis.

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[14]	36[15]	3[16]	7[17]
Units: percentage of participants				
number (not applicable)				
SCLC; Group B, n=0, 0, 0, 18, 1, 3	9999	0.0	0.0	0.0
Ewing's sarcoma; Group B, n=0, 0, 0, 3, 0, 0	9999	0.0	9999	9999
PDNTs; Group B, n=1, 0, 0, 12, 0, 0	9999	0.0	9999	9999
Other solid tumors; Group B, n=2, 3, 1, 3, 2, 4	0.0	0.0	50.0	0.0

Notes:

[14] - Only participants with the indicated type of solid tumor contributed to the analysis.

[15] - Only participants with the indicated type of solid tumor contributed to the analysis.

[16] - Only participants with the indicated type of solid tumor contributed to the analysis.

[17] - Only participants with the indicated type of solid tumor contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with acute myeloid leukemia (AML) who received INCB059872 monotherapy

End point title	ORR for altering the natural history of the disease in participants with acute myeloid leukemia (AML) who received INCB059872 monotherapy[18]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission or complete remission with incomplete hematologic recovery (CRi), per the International Working Group Response Criteria for AML, recorded before and including the first event of progression (treatment failure, relapse, and PD) based on altering the natural history of the disease. Complete remission: absolute neutrophil count (ANC) ≥1.0 x 10^9/Liter (L), platelet count ≥100 x 10^9/L, bone marrow with less than 5% blast cells, Auer rods not detectable; no platelet, or whole blood transfusions for 7 days prior to the date of the hematology assessment. CRi: complete remission, but the ANC count may be < 1.0 x 10^9/L and/or the platelet count may be <100 x 10^9/L.

End point type	Secondary

End point timeframe:

up to 85 days

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[19]	5[20]	0[21]	4[22]
Units: percentage of participants				
number (not applicable)	0.0	0.0		0.0

Notes:

[19] - Only participants with AML contributed to the analysis.

[20] - Only participants with AML contributed to the analysis.

[21] - This participant was on treatment for less than a week and therefore was not evaluated for efficacy.

[22] - Only participants with AML contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12[23]	2[24]	0[25]	0[26]
Units: percentage of participants				
number (not applicable)	0.0	0.0		

Notes:

[23] - Only participants with AML contributed to the analysis.

[24] - Only participants with AML contributed to the analysis.

[25] - Participants did not have AML and thus did not contribute to the analysis.

[26] - Participants did not have AML and thus did not contribute to the analysis.

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]
Units: percentage of participants				
number (not applicable)				

Notes:

[27] - Participants did not have AML and thus did not contribute to the analysis.

[28] - Participants did not have AML and thus did not contribute to the analysis.

[29] - Participants did not have AML and thus did not contribute to the analysis.

[30] - Participants did not have AML and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with myelodysplastic syndrome (MDS) who received INCB059872 monotherapy

End point title	ORR for altering the natural history of the disease in participants with myelodysplastic syndrome (MDS) who received INCB059872 monotherapy[31]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission, partial remission, or bone marrow complete remission, per the International Working Group Response Criteria for MDS, recorded before and including the first event of progression (treatment failure, relapse after CR or PR, disease transformation, and PD) based on altering the natural history of the disease. Complete remission: <5% bone marrow blasts without evidence of dysplasia; peripheral blood counts: hemoglobin ≥11 grams per deciliter (g/dL), neutrophils ≥1 x 10^9/L, platelets ≥100 x 10^9/L. Partial remission: meeting complete remission criteria, but bone marrow blasts decreased by ≥50% from pre-treatment, but still ≥5%. Bone marrow complete remission: ≤5% bone marrow blasts and decrease by ≥50% from pre-treatment.

End point type	Secondary

End point timeframe:

up to 61 days

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[32]	1	0[33]	1
Units: percentage of participants				
number (not applicable)		0.0		0.0

Notes:

[32] - Participants did not have MDS and thus did not contribute to the analysis.

[33] - This participant was on treatment for less than a week and therefore was not evaluated for efficacy.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	0[34]	0[35]	0[36]
Units: percentage of participants				
number (not applicable)	0.0			

Notes:

[34] - Participants did not have MDS and thus did not contribute to the analysis.

[35] - Participants did not have MDS and thus did not contribute to the analysis.

[36] - Participants did not have MDS and thus did not contribute to the analysis.

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[37]	0[38]	0[39]	0[40]
Units: percentage of participants				
number (not applicable)				

Notes:

[37] - Participants did not have MDS and thus did not contribute to the analysis.

[38] - Participants did not have MDS and thus did not contribute to the analysis.

[39] - Participants did not have MDS and thus did not contribute to the analysis.

[40] - Participants did not have MDS and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in spleen volume reduction (SVR) at Week 12 in participants with myelofibrosis (MF) who received INCB059872 monotherapy

End point title	Change from Baseline in spleen volume reduction (SVR) at Week 12 in participants with myelofibrosis (MF) who received INCB059872 monotherapy[41]

End point description:

Change from Baseline was to have been calculated as the post-Baseline value minus the Baseline value. SVR was to have been measured by magnetic resonance imaging (MRI), or by computed tomography (CT) scan in participants who were not candidates for MRI or when MRI was not readily available.

End point type	Secondary

End point timeframe:

Baseline; Week 12

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[42]	0[43]	0[44]	0[45]
Units: centimeters cubed				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[42] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[43] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[44] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[45] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[46]	0[47]	0[48]	0[49]
Units: centimeters cubed				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[46] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[47] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[48] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[49] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: centimeters cubed				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[50] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[51] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[52] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

[53] - Analysis was not conducted because no participants with MF remained in the study at Week 12.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of INCB059872 in plasma when received as monotherapy

End point title	Cmax of INCB059872 in plasma when received as

End point description:

Cmax was defined as the maximum observed plasma concentration of INCB059872. 9999=Mean (SD) cannot be reported for a single participant.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

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

Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	0[55]	3
Units: nanomolar (nM)				
arithmetic mean (standard deviation)	33.4 (± 29.2)	46.0 (± 12.5)	()	73.1 (± 30.5)

Notes:

[55] - No participants contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	3
Units: nanomolar (nM)				
arithmetic mean (standard deviation)	110 (± 13.7)	9999 (± 9999)	25.7 (± 21.8)	46.0 (± 9.95)

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[56]	6	1	3
Units: nanomolar (nM)				
arithmetic mean (standard deviation)	()	70.6 (± 25.6)	9999 (± 9999)	98.2 (± 28.5)

Notes:

[56] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of INCB059872 in plasma when received as monotherapy

End point title	tmax of INCB059872 in plasma when received as

End point description:

tmax was defined as the time to the maximum observed plasma concentration of INCB059872.
9999=Median (full range) cannot be reported for a single participant.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

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

Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	0[58]	3
Units: hours				
median (full range (min-max))	0.5 (0.5 to 0.5)	1 (0.5 to 1)	(to)	1 (0.5 to 1)

Notes:

[58] - No participants contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	3	3
Units: hours				
median (full range (min-max))	0.5 (0.5 to 1)	9999 (9999 to 9999)	2.0 (0.5 to 2)	2 (0.5 to 2)

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[59]	6	1	3
Units: hours				
median (full range (min-max))	(to)	1 (0.5 to 2)	9999 (9999 to 9999)	0.5 (0.5 to 1)

Notes:

[59] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-τ) of INCB059872 in plasma when received as monotherapy

End point title	AUC(0-τ) of INCB059872 in plasma when received as monotherapy[60]

End point description:

AUC(0-τ) was defined as the area under the plasma concentration-time curve from time = 0 to the end of the dosing period of INCB059872. 9999=Mean (SD) cannot be reported for a single participant.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

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

Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	0[61]	3
Units: nM x hour				
arithmetic mean (standard deviation)	196 (± 8.38)	216 (± 75.5)	()	374 (± 120)

Notes:

[61] - No participants contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	1
Units: nM x hour				
arithmetic mean (standard deviation)	486 (± 107)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[62]	6	1	3
Units: nM x hour				
arithmetic mean (standard deviation)	()	361 (± 115)	9999 (± 9999)	495 (± 63.2)

Notes:

[62] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of INCB059872 in plasma when received as monotherapy

End point title	t1/2 of INCB059872 in plasma when received as

End point description:

t1/2 was defined as the half-life of INCB059872. 9999=Mean (SD) cannot be reported for a single participant.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

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

Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	0[64]	3
Units: hours				
arithmetic mean (standard deviation)	3.15 (± 0.189)	3.30 (± 0.765)	()	3.13 (± 0.495)

Notes:

[64] - No participants contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	1
Units: hours				
arithmetic mean (standard deviation)	3.67 (± 1.38)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[65]	6	1	3
Units: hours				
arithmetic mean (standard deviation)	()	3.57 (± 0.52)	9999 (± 9999)	4.28 (± 0.25)

Notes:

[65] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: CL/F of INCB059872 in plasma when received as monotherapy

End point title	CL/F of INCB059872 in plasma when received as

End point description:

CL/F was defined as the apparent oral clearance of INCB059872. 9999=Mean (SD) cannot be reported for a single participant.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group A: INCB059872 Monotherapy; 2 mg QOD	Group A: INCB059872 Monotherapy; 2 mg QD	Group A: INCB059872 Monotherapy; 3 mg QOD	Group A: INCB059872 Monotherapy; 3 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	4	0[67]	3
Units: Liters per hour				
arithmetic mean (standard deviation)	32.9 (± 7.94)	26.3 (± 9.31)	()	22.1 (± 6.56)

Notes:

[67] - No participants contributed to the analysis.

End point values	Group A: INCB059872 Monotherapy; 4 mg QD	Group A: INCB059872 Monotherapy; 5 mg QD	Group B: INCB059872 Monotherapy; 1 mg QD	Group B: INCB059872 Monotherapy; 2 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	1	1
Units: Liters per hour				
arithmetic mean (standard deviation)	22.1 (± 5.57)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)

End point values	Group B: INCB059872 Monotherapy; 2 mg QD	Group B: INCB059872 Monotherapy; 3 mg QOD	Group B: INCB059872 Monotherapy; 3 mg QD	Group B: INCB059872 Monotherapy; 4 mg QOD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[68]	6	1	3
Units: Liters per hour				
arithmetic mean (standard deviation)	()	23.1 (± 6.32)	9999 (± 9999)	21.1 (± 2.74)

Notes:

[68] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in participants with SCLC who received combination therapy

End point title	ORR in participants with SCLC who received combination therapy[69]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of CR or a PR, per investigator assessment according to RESIST v1.1, recorded before and including the first event of PD. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions.

End point type	Secondary

End point timeframe:

up to 1353 days

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[70]	0[71]	0[72]	0[73]
Units: percentage of participants				
number (not applicable)				

Notes:

[70] - Participants did not have SCLC and thus did not contribute to the analysis.

[71] - Participants did not have SCLC and thus did not contribute to the analysis.

[72] - Participants did not have SCLC and thus did not contribute to the analysis.

[73] - Participants did not have SCLC and thus did not contribute to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[74]	5[75]		
Units: percentage of participants				
number (not applicable)		20.0		

Notes:

[74] - Participants did not have SCLC and thus did not contribute to the analysis.

[75] - Only participants with available data contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with AML who received combination therapy

End point title	ORR for altering the natural history of the disease in participants with AML who received combination therapy[76]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission or CRi, per the International Working Group Response Criteria for AML, recorded before and including the first event of progression (treatment failure, relapse, and PD) based on altering the natural history of the disease. Complete remission: ANC ≥1.0 x 10^9/L, platelet count ≥100 x 10^9/L, bone marrow with less than 5% blast cells, Auer rods not detectable; no platelet, or whole blood transfusions for 7 days prior to the date of the hematology assessment. CRi: complete remission, but the ANC count may be < 1.0 x 10^9/L and/or the platelet count may be <100 x 10^9/L.

End point type	Secondary

End point timeframe:

up to 208 days

Notes:

[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	1	6[77]
Units: percentage of participants				
number (not applicable)	20.0	0.0	0.0	16.7

Notes:

[77] - Only participants with AML contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1[78]	0[79]		
Units: percentage of participants				
number (not applicable)	0.0			

Notes:

[78] - Only participants with AML contributed to the analysis.

[79] - Participants did not have AML and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of INCB059872 in plasma when received as combination therapy

End point title	Cmax of INCB059872 in plasma when received as combination therapy[80]

End point description:

Cmax was defined as the maximum observed plasma concentration of INCB059872.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[81]	3
Units: nM				
arithmetic mean (standard deviation)	44.3 (± 16.4)	96.4 (± 10.7)	()	38.2 (± 33.5)

Notes:

[81] - No participants contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[82]	5		
Units: nM				
arithmetic mean (standard deviation)	()	78.0 (± 26.3)		

Notes:

[82] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: ORR for altering the natural history of the disease in participants with MDS who received combination therapy

End point title	ORR for altering the natural history of the disease in participants with MDS who received combination therapy[83]

End point description:

ORR was defined as the percentage of participants who achieved a best overall response of complete remission, partial remission, or bone marrow complete remission, per the International Working Group Response Criteria for MDS, recorded before and including the first event of progression (treatment failure, relapse after CR or PR, disease transformation, and PD) based on altering the natural history of the disease. Complete remission: <5% bone marrow blasts without evidence of dysplasia; peripheral blood counts: hemoglobin ≥11 g/dL, neutrophils ≥1 x 10^9/L, platelets ≥100 x 10^9/L. Partial remission: meeting complete remission criteria, but bone marrow blasts decreased by ≥50% from pre-treatment, but still ≥5%. Bone marrow complete remission: ≤5% bone marrow blasts and decrease by ≥50% from pre-treatment.

End point type	Secondary

End point timeframe:

up to 85 days

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[84]	0[85]	0[86]	1[87]
Units: percentage of participants				
number (not applicable)				0.0

Notes:

[84] - Participants did not have MDS and thus did not contribute to the analysis.

[85] - Participants did not have MDS and thus did not contribute to the analysis.

[86] - Participants did not have MDS and thus did not contribute to the analysis.

[87] - Only participants with MDS contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[88]	0[89]		
Units: percentage of participants				
number (not applicable)				

Notes:

[88] - Only participants with MDS contributed to the analysis.

[89] - Participants did not have MDS and thus did not contribute to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of INCB059872 in plasma when received as combination therapy

End point title	tmax of INCB059872 in plasma when received as combination therapy[90]

End point description:

tmax was defined as the time to the maximum observed plasma concentration of INCB059872.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[91]	3
Units: hours				

median (full range (min-max))	1.0 (0.5 to 1)	0.5 (0.5 to 0.5)	(to)	0.5 (0 to 1)

Notes:

[91] - No participants contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[92]	5		
Units: hours				
median (full range (min-max))	(to)	1.0 (0.5 to 1)		

Notes:

[92] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-τ) of INCB059872 in plasma when received as combination therapy

End point title	AUC(0-τ) of INCB059872 in plasma when received as combination therapy[93]

End point description:

AUC(0-τ) was defined as the area under the plasma concentration-time curve from time = 0 to the end of the dosing period of INCB059872.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[93] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[94]	3
Units: nM x hour				
arithmetic mean (standard deviation)	225 (± 85.9)	377 (± 25.7)	()	273 (± 24.4)

Notes:

[94] - No participants contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[95]	5		
Units: nM x hour				
arithmetic mean (standard deviation)	()	357 (± 97.5)		

Notes:

[95] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: t1/2 of INCB059872 in plasma when received as combination therapy

End point title	t1/2 of INCB059872 in plasma when received as combination therapy[96]

End point description:

t1/2 was defined as the half-life of INCB059872.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[97]	3
Units: hours				
arithmetic mean (standard deviation)	3.95 (± 0.499)	3.41 (± 0.281)	()	3.08 (± 0.040)

Notes:

[97] - No participants contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[98]	5		
Units: hours				
arithmetic mean (standard deviation)	()	3.79 (± 0.852)		

Notes:

[98] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: CL/F of INCB059872 in plasma when received as combination therapy

End point title	CL/F of INCB059872 in plasma when received as combination therapy[99]

End point description:

CL/F was defined as the apparent oral clearance of INCB059872.

End point type	Secondary

End point timeframe:

Cycle 1 Day 15: 0.5, 1, 2, 4, and 6 hours after INCB059872 dose

Notes:

[99] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Statistical analysis was not performed for this endpoint.

End point values	Group C: Combination Therapy; INCB059872 2 mg QD + ATRA	Group C: Combination Therapy; INCB059872 3 mg QD + ATRA	Group C: Combination Therapy; INCB059872 4 mg QD + ATRA	Group D: Combination Therapy; INCB059872 2 mg QD + azacitidine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[100]	3
Units: Liters per hour				
arithmetic mean (standard deviation)	25.1 (± 7.21)	20.7 (± 1.41)	()	19.0 (± 1.70)

Notes:

[100] - No participants contributed to the analysis.

End point values	Group D: Combination Therapy; INCB059872 3 mg QD + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[101]	5		
Units: Liters per hour				
arithmetic mean (standard deviation)	()	23.5 (± 8.14)		

Notes:

[101] - No participants contributed to the analysis.

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

up to 1387 days

Adverse event reporting additional description:

Treatment-emergent adverse events, defined as adverse events either reported for the first time or the worsening of pre-existing events after the first dose of study drug and within 30 days of the last administration of study drug, have been reported for the Safety Population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Group A: INCB059872 Monotherapy; AML or MDS

Reporting group description:

Group A: Participants with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) received oral INB059872 2 milligrams (mg) or 3 mg as monotherapy once every other day (QOD) or 2 mg, 3mg, 4 mg, or 5 mg as monotherapy once daily (QD) on a 28-day continuous therapy cycle.

Reporting group title	Group B: INCB059872 Monotherapy; SCLC/solid malignancies

Reporting group description:

Participants with small cell lung cancer (SCLC) and other solid malignancies (e.g., endocrine tumors) received oral INB059872 1 mg, 2 mg, or 3 mg as monotherapy QD or 2 mg, 3 mg, or 4 mg as monotherapy QOD on a 28-day continuous therapy cycle.

Reporting group title	Total

Reporting group description:

Total

Reporting group title	Group D: Combination Therapy; INCB059872 + azacitidine

Reporting group description:

Participants with newly diagnosed, treatment-naïve AML or MDS received INCB059872 2 mg or 3 mg QD on a 28-day continuous therapy cycle in combination with azacitidine, administered at a starting dose of 75 mg/m^2 subcutaneously or intravenously for 7 days during the first 9-day period of each 28-day treatment cycle.

Reporting group title	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab

Reporting group description:

Participants with SCLC received oral INCB059872 3 mg QOD on a 28-day continuous therapy cycle in combination with nivolumab, administered at 3 mg/kilogram (kg) intravenously over 60 minutes every 2 weeks of each 28-day treatment cycle.

Reporting group title	Group C: Combination Therapy; INCB059872 + ATRA

Reporting group description:

Participants with relapsed/refractory AML received oral INCB059872 2 mg, 3 mg, or 4 mg QD in combination with all-trans retinoic acid (ATRA) (at a starting dose of 45 mg/meters squared [m^2] per day at 2 evenly divided doses) on a 28-day continuous therapy cycle.

Serious adverse events	Group A: INCB059872 Monotherapy; AML or MDS	Group B: INCB059872 Monotherapy; SCLC/solid malignancies	Total
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 35 (60.00%)	33 / 53 (62.26%)	71 / 115 (61.74%)

number of deaths (all causes)	28	40	87
number of deaths resulting from adverse events	7	6	16
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Blast cell crisis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Metastases to central nervous system			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
General disorders and administration site conditions			

General physical health deterioration			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
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 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
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 failure			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 35 (0.00%)	3 / 53 (5.66%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hypoxia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1

Pulmonary embolism			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 4
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 35 (2.86%)	2 / 53 (3.77%)	3 / 115 (2.61%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac disorders			
Atrial fibrillation			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
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			
Headache			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	10 / 35 (28.57%)	1 / 53 (1.89%)	17 / 115 (14.78%)
occurrences causally related to treatment / all	0 / 14	0 / 1	1 / 23
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Leukocytosis			
subjects affected / exposed	3 / 35 (8.57%)	0 / 53 (0.00%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Thrombocytopenia			
subjects affected / exposed	3 / 35 (8.57%)	1 / 53 (1.89%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	2 / 3	1 / 1	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 35 (0.00%)	4 / 53 (7.55%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Nausea			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences causally related to treatment / all	2 / 2	0 / 2	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 35 (2.86%)	2 / 53 (3.77%)	3 / 115 (2.61%)
occurrences causally related to treatment / all	1 / 1	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			

subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	1 / 35 (2.86%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
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	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia			
subjects affected / exposed	4 / 35 (11.43%)	3 / 53 (5.66%)	9 / 115 (7.83%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Perirectal abscess			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Staphylococcal skin infection			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group D: Combination Therapy; INCB059872 + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab	Group C: Combination Therapy; INCB059872 + ATRA
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 8 (87.50%)	2 / 6 (33.33%)	8 / 13 (61.54%)
number of deaths (all causes)	4	3	12
number of deaths resulting from adverse events	0	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Blast cell crisis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Malignant neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Shock haemorrhagic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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			
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
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 failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 alveolar haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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			
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (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

Spinal compression fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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			
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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

Myasthenic syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	5 / 13 (38.46%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Pancreatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Swollen tongue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Tongue haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Cholangitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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			
Acute febrile neutrophilic dermatosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Rash maculo-papular			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Myositis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 fungal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirectal abscess			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (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
Septic shock			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Staphylococcal skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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 bacterial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Tooth infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Decreased appetite			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Hypervolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (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

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

Non-serious adverse events	Group A: INCB059872 Monotherapy; AML or MDS	Group B: INCB059872 Monotherapy; SCLC/solid malignancies	Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 35 (97.14%)	51 / 53 (96.23%)	111 / 115 (96.52%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences (all)	0	1	2
Hypotension			
subjects affected / exposed	3 / 35 (8.57%)	1 / 53 (1.89%)	5 / 115 (4.35%)
occurrences (all)	3	1	5
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences (all)	2	2	4
Chest pain			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Fatigue			
subjects affected / exposed	12 / 35 (34.29%)	27 / 53 (50.94%)	50 / 115 (43.48%)
occurrences (all)	12	31	55
Influenza like illness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	2
Injection site erythema			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	4
Oedema peripheral			
subjects affected / exposed	3 / 35 (8.57%)	3 / 53 (5.66%)	9 / 115 (7.83%)
occurrences (all)	4	3	10
Oedema			
subjects affected / exposed	4 / 35 (11.43%)	0 / 53 (0.00%)	4 / 115 (3.48%)
occurrences (all)	4	0	4
Pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Peripheral swelling			
subjects affected / exposed	1 / 35 (2.86%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences (all)	1	2	4
Pyrexia			
subjects affected / exposed	1 / 35 (2.86%)	3 / 53 (5.66%)	4 / 115 (3.48%)
occurrences (all)	1	3	4
Reproductive system and breast disorders			
Vaginal haemorrhage			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 35 (11.43%)	6 / 53 (11.32%)	13 / 115 (11.30%)
occurrences (all)	4	6	15
Dyspnoea			
subjects affected / exposed	4 / 35 (11.43%)	8 / 53 (15.09%)	14 / 115 (12.17%)
occurrences (all)	4	8	14
Dyspnoea exertional			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	1 / 35 (2.86%)	2 / 53 (3.77%)	9 / 115 (7.83%)
occurrences (all)	1	3	11
Hiccups			
subjects affected / exposed	0 / 35 (0.00%)	3 / 53 (5.66%)	3 / 115 (2.61%)
occurrences (all)	0	3	3
Hypoxia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	2	1	3
Nasal congestion			
subjects affected / exposed	1 / 35 (2.86%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	1	1	3
Oropharyngeal pain			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	2	1	3
Pulmonary hypertension			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	3 / 35 (8.57%)	1 / 53 (1.89%)	6 / 115 (5.22%)
occurrences (all)	3	1	6
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 35 (0.00%)	3 / 53 (5.66%)	3 / 115 (2.61%)
occurrences (all)	0	3	3
Insomnia			
subjects affected / exposed	1 / 35 (2.86%)	5 / 53 (9.43%)	8 / 115 (6.96%)
occurrences (all)	1	5	8
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 35 (2.86%)	2 / 53 (3.77%)	5 / 115 (4.35%)
occurrences (all)	1	2	5
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 35 (0.00%)	5 / 53 (9.43%)	6 / 115 (5.22%)
occurrences (all)	0	6	7
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	2	1	3
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 35 (5.71%)	4 / 53 (7.55%)	6 / 115 (5.22%)
occurrences (all)	2	4	6
Blood bilirubin increased			
subjects affected / exposed	0 / 35 (0.00%)	3 / 53 (5.66%)	5 / 115 (4.35%)
occurrences (all)	0	4	6
Blood creatinine increased			
subjects affected / exposed	3 / 35 (8.57%)	3 / 53 (5.66%)	7 / 115 (6.09%)
occurrences (all)	3	3	8
Blood triglycerides increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Lymphocyte count decreased			

subjects affected / exposed	3 / 35 (8.57%)	2 / 53 (3.77%)	6 / 115 (5.22%)
occurrences (all)	3	3	7
Neutrophil count decreased			
subjects affected / exposed	2 / 35 (5.71%)	6 / 53 (11.32%)	11 / 115 (9.57%)
occurrences (all)	2	8	13
Platelet count decreased			
subjects affected / exposed	5 / 35 (14.29%)	13 / 53 (24.53%)	22 / 115 (19.13%)
occurrences (all)	5	16	27
Troponin increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	5 / 35 (14.29%)	5 / 53 (9.43%)	14 / 115 (12.17%)
occurrences (all)	5	5	14
White blood cell count decreased			
subjects affected / exposed	1 / 35 (2.86%)	4 / 53 (7.55%)	6 / 115 (5.22%)
occurrences (all)	1	6	8
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	4 / 115 (3.48%)
occurrences (all)	2	1	4
Fall			
subjects affected / exposed	2 / 35 (5.71%)	4 / 53 (7.55%)	8 / 115 (6.96%)
occurrences (all)	2	4	8
Skin laceration			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences (all)	0	1	2
Subcutaneous haematoma			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Transfusion reaction			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	3
Cardiac disorders			

Atrial enlargement			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	1 / 35 (2.86%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	1	1	3
Pericardial effusion			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Sinus tachycardia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	4 / 115 (3.48%)
occurrences (all)	2	1	4
Tricuspid valve incompetence			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	3 / 35 (8.57%)	0 / 53 (0.00%)	3 / 115 (2.61%)
occurrences (all)	3	0	3
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	3 / 35 (8.57%)	3 / 53 (5.66%)	6 / 115 (5.22%)
occurrences (all)	3	3	6
Dysgeusia			
subjects affected / exposed	6 / 35 (17.14%)	10 / 53 (18.87%)	20 / 115 (17.39%)
occurrences (all)	6	10	20
Headache			
subjects affected / exposed	6 / 35 (17.14%)	1 / 53 (1.89%)	12 / 115 (10.43%)
occurrences (all)	6	1	13
Neuropathy peripheral			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Paraesthesia			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	0 / 35 (0.00%)	5 / 53 (9.43%)	5 / 115 (4.35%)
occurrences (all)	0	5	5
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 35 (31.43%)	6 / 53 (11.32%)	20 / 115 (17.39%)
occurrences (all)	11	7	21
Febrile neutropenia			
subjects affected / exposed	4 / 35 (11.43%)	0 / 53 (0.00%)	5 / 115 (4.35%)
occurrences (all)	4	0	7
Leukopenia			
subjects affected / exposed	3 / 35 (8.57%)	2 / 53 (3.77%)	6 / 115 (5.22%)
occurrences (all)	3	3	7
Lymph node pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	5 / 35 (14.29%)	7 / 53 (13.21%)	13 / 115 (11.30%)
occurrences (all)	5	8	14
Thrombocytopenia			
subjects affected / exposed	7 / 35 (20.00%)	14 / 53 (26.42%)	30 / 115 (26.09%)
occurrences (all)	10	19	49
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Hypoacusis			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	2
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Eye inflammation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Vitreous floaters			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences (all)	2	3	5
Abdominal pain			
subjects affected / exposed	2 / 35 (5.71%)	7 / 53 (13.21%)	10 / 115 (8.70%)
occurrences (all)	2	7	10
Constipation			
subjects affected / exposed	5 / 35 (14.29%)	11 / 53 (20.75%)	23 / 115 (20.00%)
occurrences (all)	5	13	25
Diarrhoea			
subjects affected / exposed	7 / 35 (20.00%)	9 / 53 (16.98%)	20 / 115 (17.39%)
occurrences (all)	7	10	21
Dyspepsia			

subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Dysphagia			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	3 / 115 (2.61%)
occurrences (all)	2	0	3
Dry mouth			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	7 / 115 (6.09%)
occurrences (all)	2	2	7
Gingival bleeding			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Flatulence			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Gingival hypertrophy			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Lip dry			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	3 / 115 (2.61%)
occurrences (all)	1	0	3
Nausea			
subjects affected / exposed	11 / 35 (31.43%)	14 / 53 (26.42%)	31 / 115 (26.96%)
occurrences (all)	11	15	34
Oesophagitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Oral blood blister			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	2
Oral disorder			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Paraesthesia oral			

subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	2 / 35 (5.71%)	4 / 53 (7.55%)	11 / 115 (9.57%)
occurrences (all)	2	4	11
Vomiting			
subjects affected / exposed	10 / 35 (28.57%)	8 / 53 (15.09%)	21 / 115 (18.26%)
occurrences (all)	11	8	24
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences (all)	0	1	2
Blister			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	6 / 115 (5.22%)
occurrences (all)	2	1	6
Ecchymosis			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	4 / 115 (3.48%)
occurrences (all)	2	2	4
Nail disorder			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	5 / 115 (4.35%)
occurrences (all)	3	1	6
Skin irritation			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	2
Rash pruritic			

subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences (all)	0	1	2
Rash			
subjects affected / exposed	2 / 35 (5.71%)	1 / 53 (1.89%)	7 / 115 (6.09%)
occurrences (all)	2	1	7
Rash erythematous			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	4 / 115 (3.48%)
occurrences (all)	2	0	4
Skin lesion			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Nocturia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	3 / 115 (2.61%)
occurrences (all)	0	2	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	7 / 35 (20.00%)	6 / 53 (11.32%)	18 / 115 (15.65%)
occurrences (all)	7	6	19
Arthritis			

subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	2 / 115 (1.74%)
occurrences (all)	0	1	2
Back pain			
subjects affected / exposed	3 / 35 (8.57%)	4 / 53 (7.55%)	8 / 115 (6.96%)
occurrences (all)	3	5	9
Muscular weakness			
subjects affected / exposed	1 / 35 (2.86%)	4 / 53 (7.55%)	5 / 115 (4.35%)
occurrences (all)	1	5	6
Musculoskeletal chest pain			
subjects affected / exposed	0 / 35 (0.00%)	2 / 53 (3.77%)	3 / 115 (2.61%)
occurrences (all)	0	2	3
Myalgia			
subjects affected / exposed	1 / 35 (2.86%)	3 / 53 (5.66%)	8 / 115 (6.96%)
occurrences (all)	1	3	8
Neck pain			
subjects affected / exposed	2 / 35 (5.71%)	2 / 53 (3.77%)	6 / 115 (5.22%)
occurrences (all)	2	2	6
Pain in jaw			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Pain in extremity			
subjects affected / exposed	4 / 35 (11.43%)	0 / 53 (0.00%)	6 / 115 (5.22%)
occurrences (all)	4	0	6
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 53 (1.89%)	3 / 115 (2.61%)
occurrences (all)	0	1	4
Catheter site cellulitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Fungal infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1

Gingivitis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	1	0	2
Herpes simplex			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	0	0	2
Oral herpes			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 53 (0.00%)	1 / 115 (0.87%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 35 (28.57%)	10 / 53 (18.87%)	25 / 115 (21.74%)
occurrences (all)	10	10	25
Hypocalcaemia			
subjects affected / exposed	2 / 35 (5.71%)	0 / 53 (0.00%)	2 / 115 (1.74%)
occurrences (all)	2	0	2
Hyperglycaemia			
subjects affected / exposed	4 / 35 (11.43%)	1 / 53 (1.89%)	6 / 115 (5.22%)
occurrences (all)	5	1	7
Hyperuricaemia			
subjects affected / exposed	1 / 35 (2.86%)	5 / 53 (9.43%)	7 / 115 (6.09%)
occurrences (all)	1	5	7
Hypoalbuminaemia			

subjects affected / exposed	3 / 35 (8.57%)	3 / 53 (5.66%)	8 / 115 (6.96%)
occurrences (all)	3	3	8
Hypokalaemia			
subjects affected / exposed	5 / 35 (14.29%)	3 / 53 (5.66%)	9 / 115 (7.83%)
occurrences (all)	5	3	9
Hypomagnesaemia			
subjects affected / exposed	4 / 35 (11.43%)	1 / 53 (1.89%)	6 / 115 (5.22%)
occurrences (all)	4	2	7
Hyponatraemia			
subjects affected / exposed	4 / 35 (11.43%)	5 / 53 (9.43%)	12 / 115 (10.43%)
occurrences (all)	4	5	13
Hypophosphataemia			
subjects affected / exposed	4 / 35 (11.43%)	5 / 53 (9.43%)	11 / 115 (9.57%)
occurrences (all)	4	7	15

Non-serious adverse events	Group D: Combination Therapy; INCB059872 + azacitidine	Group E: Combination Therapy; INCB059872 3 mg QOD + nivolumab	Group C: Combination Therapy; INCB059872 + ATRA
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	6 / 6 (100.00%)	12 / 13 (92.31%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Chills			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 8 (37.50%)	5 / 6 (83.33%)	3 / 13 (23.08%)
occurrences (all)	3	6	3
Influenza like illness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Injection site erythema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
Oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	0 / 13 (0.00%)
occurrences (all)	1	4	0
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Dyspnoea exertional			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	4 / 13 (30.77%)
occurrences (all)	3	0	4
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1

Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Blood triglycerides increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	1	1
Platelet count decreased			

subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	2 / 13 (15.38%)
occurrences (all)	1	3	2
Troponin increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	2 / 8 (25.00%)	2 / 6 (33.33%)	0 / 13 (0.00%)
occurrences (all)	2	2	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Skin laceration			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Subcutaneous haematoma			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Transfusion reaction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
Atrial enlargement			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pericardial effusion			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
Headache			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	2	0	4
Neuropathy peripheral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	1 / 13 (7.69%)
occurrences (all)	0	2	1
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Leukopenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	5 / 8 (62.50%)	3 / 6 (50.00%)	1 / 13 (7.69%)
occurrences (all)	12	6	2
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypoacusis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eye inflammation			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	5 / 8 (62.50%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	5	1	1
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Gingival bleeding			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Flatulence			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gingival hypertrophy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lip dry			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Mouth haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	3 / 8 (37.50%)	1 / 6 (16.67%)	2 / 13 (15.38%)
occurrences (all)	5	1	2
Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Oral blood blister			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Oral disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	3 / 13 (23.08%)
occurrences (all)	1	1	3
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	3	1	1
Hepatobiliary disorders			
Hyperbilirubinaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	3
Ecchymosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Skin irritation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 13 (7.69%)
occurrences (all)	1	2	1
Rash erythematous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0

Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Skin lesion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vitiligo			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Nocturia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	1 / 13 (7.69%)
occurrences (all)	1	4	1
Arthritis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Myalgia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	2 / 13 (15.38%)
occurrences (all)	0	2	2
Neck pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Pain in jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Catheter site cellulitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Nail infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 8 (25.00%)	3 / 6 (50.00%)	0 / 13 (0.00%)
occurrences (all)	2	3	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	1	1	2

Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 3	0 / 6 (0.00%) 0	1 / 13 (7.69%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 January 2016	The primary purpose of Amendment 1 was to delete combination therapy from the study design, refine exclusion criteria, add to the prohibited medication list, increase dose-limiting toxicity language, improve language for restarting study drug and at what increments, and add stopping rules.
28 July 2016	The primary purpose of this amendment was to update the language in the inclusion and exclusion criteria to provide more clarity, to provide additional language regarding different regimens to be explored in this study, and to update Tables 1 through 5.
22 September 2017	The primary purpose of this amendment was to add dose-finding and expansion cohorts to evaluate INCB059872 in combination with select conventional care treatment regimens in participants with select advanced malignancies and to update aspects of the monotherapy design based on emerging data from the current study.
06 November 2017	The primary purpose of this amendment was to update the selected doses for monotherapy expansion in Part 2, update the starting doses of INCB059872 in Part 3, clarify dose-limiting toxicity (DLT) evaluability criteria, add early stopping rules for futility in Part 4, adjust the endpoints, revise the eligibility criteria for Cohorts D and D1, add an internal safety committee, and remove references to a pharmacologically active dose.
30 July 2018	The primary purpose of this amendment was to update and add treatment modification guidance for serious adverse events (SAEs) with suspected causal relationship to study drug.
16 April 2019	The primary purpose of this amendment was to update Treatment Group D to include myelodysplastic syndrome (MDS) participants, update dose interruption and modification guidance, update inclusion criteria, and update the schedule of assessments for myelofibrosis (MF) participants.
13 June 2019	The primary purpose of this amendment was to include additional safety monitoring and modify the inclusion criteria for MDS participants in Treatment Group D for Parts 3 and 4 of the Protocol.
15 June 2020	The primary purpose of this amendment was to add a principal coordinating investigator and remove the exploratory endpoint of overall survival.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated by the sponsor due to a strategic business decision.

Notes: