Clinical trial results:
A Phase 1/2, Open-label, Multi-center Study to Assess the Safety and Tolerability of Durvalumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination Therapy in Subjects With Lymphoma or Chronic Lymphocitic Leukemia

Summary

EudraCT number	2015-003516-21
Trial protocol	GB DE NL IT
Global end of trial date	21 August 2022

Results information

Result version number	v1
This version publication date	06 September 2023
First version publication date	06 September 2023

Trial information

Trial identification

Sponsor protocol code	MEDI4736-NHL-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02733042
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of durvalumab when given in combination with lenalidomide and rituximab; ibrutinib; or bendamustine and rituximab in participants with lymphoma or chronic lymphocytic leukemia.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 22
Country: Number of subjects enrolled	Italy: 23
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	United Kingdom: 18
Country: Number of subjects enrolled	United States: 25
Country: Number of subjects enrolled	Netherlands: 6
Worldwide total number of subjects	106
EEA total number of subjects	51

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	44
From 65 to 84 years	62
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

106 participants were treated.

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	Part 1 Arm A: DUR 1500 + LEN 20

Arm description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

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

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375

Arm description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

Arm title	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375

Arm description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

Investigational medicinal product name	Lenalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

Arm title	Part 1 Arm B: DUR 1500 + IBR 420

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Arm type	Experimental

Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Ibrutinib (IBR) 420 mg orally once daily

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 1 Arm B: DUR 1500 + IBR 560

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

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

Dosage and administration details:

Ibrutinib (IBR) 560 mg orally once daily

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 1 Arm C: DUR 1500 + RIT 375

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details: Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 1 Arm C: DUR 1500 + BEN 70
Arm description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Arm type	Experimental
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use
Dosage and administration details: Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Arm title	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Arm description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use
Dosage and administration details: Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the	

rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Arm title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Arm description:	
Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).	
Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13	
Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use
Dosage and administration details:	
Bendamustine (BEN) 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.	
Investigational medicinal product name	Rituximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).	
Arm title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420
Arm description:	
Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.	
Arm type	Experimental
Investigational medicinal product name	Ibrutinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
Ibrutinib (IBR) 420 mg orally once daily	
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm B MCL: DUR 1500 + IBR 560

Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

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

Dosage and administration details:

Ibrutinib (IBR) 560 mg orally once daily

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70

Arm description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

Arm title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70

Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravesical use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6

Arm title	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70

Arm description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravesical use

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

Arm title	Part 2 Arm D FL: DUR 1500

Arm description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm D DLBCL: DUR 1500

Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm D CLL/SLL: DUR 1500

Arm description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm D MCL: DUR 1500

Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Arm title	Part 2 Arm D HL: DUR 1500

Arm description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

Number of subjects in period 1	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
Started	3	3	8
Entered follow-up	3	3	6
Completed	0	1	1
Not completed	3	2	7
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	2
Adverse event, non-fatal	1	-	1
Other Reasons	-	-	1
Progressive Disease	2	1	3

Number of subjects in period 1	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375
Started	3	4	3
Entered follow-up	3	2	2
Completed	0	1	0
Not completed	3	3	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	1	-	-
Other Reasons	-	-	-
Progressive Disease	1	2	3

Number of subjects in period 1	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90

Started	1	4	5
Entered follow-up	0	4	4
Completed	0	1	0
Not completed	1	3	5
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	-	-
Other Reasons	-	-	-
Progressive Disease	-	3	3

Number of subjects in period 1	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Started	10	10	10
Entered follow-up	4 [1]	5	9
Completed	6	4	4
Not completed	4	6	6
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	1	-	2
Adverse event, non-fatal	-	2	2
Other Reasons	1	1	-
Progressive Disease	2	2	2

Number of subjects in period 1	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500
Started	10	5	5
Entered follow-up	9	4	1
Completed	1	1	0
Not completed	9	4	5
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	-	2	-
Other Reasons	-	-	-
Progressive Disease	8	1	4

Number of subjects in period 1	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500
Started	10	2	5
Entered follow-up	5	0	3
Completed	0	0	0
Not completed	10	2	5
Adverse event, serious fatal	2	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	1
Other Reasons	1	-	1

Progressive Disease	7	2	3

Number of subjects in period 1	Part 2 Arm D HL: DUR 1500
Started	5
Entered follow-up	2
Completed	1
Not completed	4
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Other Reasons	-
Progressive Disease	4

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 106 participants were treated. 69 participants entered follow-up period after completing or discontinuing study treatment.

Reporting groups

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20

Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375

Reporting group description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 420

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 560

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + BEN 70

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

Reporting group title	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420

Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm B MCL: DUR 1500 + IBR 560

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70

Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 2 Arm D FL: DUR 1500

Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D DLBCL: DUR 1500

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D CLL/SLL: DUR 1500

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D MCL: DUR 1500

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D HL: DUR 1500

Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375
Number of subjects	3	3	8
Age Categorical Units: participants			
< 65 Years	1	1	2
≥ 65 Years	2	2	6
Age Continuous Units: years			
median	71.0	66.0	77.0
full range (min-max)	50 to 78	52 to 75	53 to 80

Sex: Female, Male Units: participants			
Female	1	0	2
Male	2	3	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	2	7
Unknown or Not Reported	1	1	1
Race/Ethnicity, Customized Units: Subjects			
White	2	2	3
Asian	0	0	3
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	1
Not Collected or Reported	1	1	1
Histology Units: Subjects			
Follicular lymphoma	1	3	1
Diffuse large B-cell lymphoma	2	0	4
Marginal zone lymphoma	0	0	2
Transformed follicular lymphoma	0	0	1
Mantle cell lymphoma	0	0	0
CLL / SLL	0	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	2	2
1 - Restricted but ambulatory	3	1	4
2 - Ambulatory but unable to work	0	0	2
3 - Limited self-care	0	0	0

Reporting group values	Part 1 Arm B: DUR 1500 + IBR 420	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375
Number of subjects	3	4	3
Age Categorical Units: participants			
< 65 Years	2	1	0
≥ 65 Years	1	3	3
Age Continuous Units: years			
median	58.0	68.0	79.0
full range (min-max)	54 to 74	57 to 81	76 to 80

Sex: Female, Male Units: participants			
Female	0	2	2
Male	3	2	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	3	1
Unknown or Not Reported	1	0	2
Race/Ethnicity, Customized Units: Subjects			
White	2	4	0
Asian	0	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	1	0	3
Histology Units: Subjects			
Follicular lymphoma	1	0	1
Diffuse large B-cell lymphoma	0	0	2
Marginal zone lymphoma	0	3	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	1	1	0
CLL / SLL	1	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	1	1
1 - Restricted but ambulatory	3	3	2
2 - Ambulatory but unable to work	0	0	0
3 - Limited self-care	0	0	0

Reporting group values	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90
Number of subjects	1	4	5
Age Categorical Units: participants			
< 65 Years	0	1	3
≥ 65 Years	1	3	2
Age Continuous Units: years			
median	70.0	68.0	38.0
full range (min-max)	70 to 70	52 to 78	21 to 77

Sex: Female, Male Units: participants			
Female	0	1	3
Male	1	3	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	3	3
Unknown or Not Reported	0	1	2
Race/Ethnicity, Customized Units: Subjects			
White	1	0	4
Asian	0	3	1
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	0	1	0
Histology Units: Subjects			
Follicular lymphoma	0	1	0
Diffuse large B-cell lymphoma	1	3	5
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	0
CLL / SLL	0	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	0	3	2
1 - Restricted but ambulatory	0	0	2
2 - Ambulatory but unable to work	1	1	1
3 - Limited self-care	0	0	0

Reporting group values	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Number of subjects	10	10	10
Age Categorical Units: participants			
< 65 Years	4	2	5
≥ 65 Years	6	8	5
Age Continuous Units: years			
median	68.0	73.5	64.5
full range (min-max)	55 to 73	54 to 84	45 to 75

Sex: Female, Male Units: participants			
Female	3	1	3
Male	7	9	7
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	7	6
Unknown or Not Reported	5	3	4
Race/Ethnicity, Customized Units: Subjects			
White	5	6	4
Asian	0	1	1
Black or African American	0	0	1
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	5	3	4
Histology Units: Subjects			
Follicular lymphoma	0	0	10
Diffuse large B-cell lymphoma	0	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	10	0
CLL / SLL	10	0	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	8	6	6
1 - Restricted but ambulatory	2	3	3
2 - Ambulatory but unable to work	0	1	1
3 - Limited self-care	0	0	0

Reporting group values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500
Number of subjects	10	5	5
Age Categorical Units: participants			
< 65 Years	7	2	3
≥ 65 Years	3	3	2
Age Continuous Units: years			
median	60.0	68.0	52.0
full range (min-max)	46 to 71	53 to 79	39 to 71

Sex: Female, Male Units: participants			
Female	4	2	2
Male	6	3	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	8	3	2
Unknown or Not Reported	2	1	3
Race/Ethnicity, Customized Units: Subjects			
White	4	4	2
Asian	3	0	0
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	1	0	0
Not Collected or Reported	2	1	3
Histology Units: Subjects			
Follicular lymphoma	0	0	5
Diffuse large B-cell lymphoma	10	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	0
CLL / SLL	0	5	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	7	0	2
1 - Restricted but ambulatory	1	4	2
2 - Ambulatory but unable to work	2	1	1
3 - Limited self-care	0	0	0

Reporting group values	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500
Number of subjects	10	2	5
Age Categorical Units: participants			
< 65 Years	5	1	0
≥ 65 Years	5	1	5
Age Continuous Units: years			
median	61.5	62.0	77.0
full range (min-max)	22 to 76	55 to 69	69 to 80

Sex: Female, Male Units: participants			
Female	4	1	2
Male	6	1	3
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	9	2	5
Unknown or Not Reported	1	0	0
Race/Ethnicity, Customized Units: Subjects			
White	9	2	4
Asian	0	0	1
Black or African American	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	0	0
Not Collected or Reported	1	0	0
Histology Units: Subjects			
Follicular lymphoma	0	0	0
Diffuse large B-cell lymphoma	10	0	0
Marginal zone lymphoma	0	0	0
Transformed follicular lymphoma	0	0	0
Mantle cell lymphoma	0	0	5
CLL / SLL	0	2	0
Hodgkin lymphoma	0	0	0
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	3	1	4
1 - Restricted but ambulatory	4	1	1
2 - Ambulatory but unable to work	2	0	0
3 - Limited self-care	1	0	0

Reporting group values	Part 2 Arm D HL: DUR 1500	Total	
Number of subjects	5	106	
Age Categorical Units: participants			
< 65 Years	4	44	
≥ 65 Years	1	62	
Age Continuous Units: years			
median	51.0		
full range (min-max)	34 to 65	-	

Sex: Female, Male Units: participants			
Female	2	35	
Male	3	71	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	2	
Not Hispanic or Latino	5	76	
Unknown or Not Reported	0	28	
Race/Ethnicity, Customized Units: Subjects			
White	5	63	
Asian	0	13	
Black or African American	0	1	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Other	0	2	
Not Collected or Reported	0	27	
Histology Units: Subjects			
Follicular lymphoma	0	23	
Diffuse large B-cell lymphoma	0	37	
Marginal zone lymphoma	0	5	
Transformed follicular lymphoma	0	1	
Mantle cell lymphoma	0	17	
CLL / SLL	0	18	
Hodgkin lymphoma	5	5	
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	5	53	
1 - Restricted but ambulatory	0	39	
2 - Ambulatory but unable to work	0	13	
3 - Limited self-care	0	1	

Subject analysis sets

Subject analysis set title	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m²
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).	
Subject analysis set title	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m²
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Durvalumab + Ibrutinib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Arm C: Durvalumab + Bendamustine ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m² bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m² IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide Â± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 10 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 20 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for

any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Ibrutinib 420 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm B: Ibrutinib 560 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Reporting group values	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m²	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m²
Number of subjects	5	10	10
Age Categorical Units: participants			
< 65 Years	3	4	
≥ 65 Years	2	6	
Age Continuous Units: years			
median	38.0	68.0	30.0
full range (min-max)	21 to 77	55 to 73	6.7 to 65.2
Sex: Female, Male Units: participants			
Female	3	3	
Male	2	7	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	3	5	
Unknown or Not Reported	2	5	
Race/Ethnicity, Customized Units: Subjects			
White	4	5	
Asian	1	0	
Black or African American	0	0	
American Indian or Alaska Native	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Other	0	0	
Not Collected or Reported	0	5	
Histology Units: Subjects			
Follicular lymphoma	0	0	
Diffuse large B-cell lymphoma	5	0	
Marginal zone lymphoma	0	0	
Transformed follicular lymphoma	0	0	
Mantle cell lymphoma	0	0	

CLL / SLL	0	10	
Hodgkin lymphoma	0	0	
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active	2	8	
1 - Restricted but ambulatory	2	2	
2 - Ambulatory but unable to work	1	0	
3 - Limited self-care	0	0	

Reporting group values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab
Number of subjects	14	27	38
Age Categorical Units: participants			
< 65 Years			
≥ 65 Years			
Age Continuous Units: years			
median			
full range (min-max)			
Sex: Female, Male Units: participants			
Female			
Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White			
Asian			
Black or African American			
American Indian or Alaska Native			
Native Hawaiian or Other Pacific Islander			
Other			
Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma			
Diffuse large B-cell lymphoma			
Marginal zone lymphoma			
Transformed follicular lymphoma			
Mantle cell lymphoma			

CLL / SLL Hodgkin lymphoma			
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

Reporting group values	Arm D: Durvalumab Monotherapy	Arm D: Durvalumab Monotherapy	Arm A: Durvalumab + Lenalidomide Â± Rituximab
Number of subjects	26	25	14
Age Categorical Units: participants			
< 65 Years ≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Asian Black or African American American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma Diffuse large B-cell lymphoma Marginal zone lymphoma Transformed follicular lymphoma Mantle cell lymphoma			

CLL / SLL Hodgkin lymphoma			
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

Reporting group values	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg	Arm B: Ibrutinib 420 mg
Number of subjects	5	4	13
Age Categorical Units: participants			
< 65 Years ≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Asian Black or African American American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma Diffuse large B-cell lymphoma Marginal zone lymphoma Transformed follicular lymphoma Mantle cell lymphoma CLL / SLL			

Hodgkin lymphoma			
Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

Reporting group values	Arm B: Ibrutinib 560 mg		
Number of subjects	13		
Age Categorical Units: participants			
< 65 Years ≥ 65 Years			
Age Continuous Units: years median full range (min-max)			
Sex: Female, Male Units: participants			
Female Male			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			
Race/Ethnicity, Customized Units: Subjects			
White Asian Black or African American American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other Not Collected or Reported			
Histology Units: Subjects			
Follicular lymphoma Diffuse large B-cell lymphoma Marginal zone lymphoma Transformed follicular lymphoma Mantle cell lymphoma CLL / SLL Hodgkin lymphoma			

Eastern Cooperative Oncology Group ECOG) Performance Status			
ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead			
Units: Subjects			
0 - Fully Active 1 - Restricted but ambulatory 2 - Ambulatory but unable to work 3 - Limited self-care			

End points reporting groups

Reporting group title	Part 1 Arm A: DUR 1500 + LEN 20

Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375

Reporting group description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 420

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm B: DUR 1500 + IBR 560

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + BEN 70

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

Reporting group title	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420

Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm B MCL: DUR 1500 + IBR 560

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Reporting group title	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70

Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Reporting group title	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Reporting group title	Part 2 Arm D FL: DUR 1500

Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D DLBCL: DUR 1500

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D CLL/SLL: DUR 1500

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D MCL: DUR 1500

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Reporting group title	Part 2 Arm D HL: DUR 1500

Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

Subject analysis set title	Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m²
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Subject analysis set title	Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m²
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Durvalumab + Ibrutinib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

Subject analysis set title	Arm C: Durvalumab + Bendamustine ± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m² bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m² IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm D: Durvalumab Monotherapy
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm A: Durvalumab + Lenalidomide Â± Rituximab
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 10 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm A: Lenalidomide 20 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

Subject analysis set title	Arm B: Ibrutinib 420 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression,

unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Subject analysis set title	Arm B: Ibrutinib 560 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

Primary: Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)

End point title	Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)[1][2]

End point description:

Dose limiting toxicities were evaluated during the DLT evaluation period for participants in the dose finding cohorts. The severity grading was determined according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 4.03. A DLT is defined as below: Hematologic DLT • Grade 4 neutropenia observed for greater than 5 days duration • Grade 3 neutropenia associated with fever (≥ 38.5 °C) of any duration • Grade 4 thrombocytopenia or Grade 3 thrombocytopenia with bleeding, or any requirement for platelets transfusion • Grade 4 anemia, unexplained by underlying disease • Any other grade 4 hematologic toxicity that does not resolve to participant's pretreatment baseline level within 72 hours. Non-Hematologic DLT • Any non-hematological toxicity ≥ Grade 3 except for alopecia and nausea controlled by medical management • Any treatment interruption greater than 2 weeks due to adverse event.

End point type	Primary

End point timeframe:

Cycle 1 (28 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: Only summary statistics planned 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: Endpoints are cohort specific and do not report for all arms.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	6	3
Units: Participants	0	3	1	0

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0[3]	4
Units: Participants	0	0		0

Notes:

[3] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN			

	90			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Participants	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment-emergent Adverse Events

End point title	Number of Participants with Treatment-emergent Adverse Events[4]

End point description:

Treatment-emergent adverse events (TEAEs) are defined as adverse events (AEs) occurring or worsening on or after the first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. The intensity of AEs was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by the investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5).

End point type	Primary

End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the data cut-off date of 6 March 2019. Maximum time on treatment was 55.4 weeks for DUR and 130 weeks for other study drugs.

Notes:

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

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: Participants				
Any TEAE	3	3	8	3
TEAE Related to Any Study Drug	3	3	8	3
CTCAE Grade 3-4 TEAE	1	3	7	2
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	3	7	1
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	1	2	4	2
Serious TEAE Related to Any Study Drug	1	2	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	0	3	1
TEAE Leading to Dose Modifications of Study Drug	1	3	3	3

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: Participants				
Any TEAE	4	3	1	4
TEAE Related to Any Study Drug	4	3	0	4
CTCAE Grade 3-4 TEAE	3	2	1	3
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	2	0	2
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	2	2	1	1
Serious TEAE Related to Any Study Drug	0	1	0	0
TEAE Leading to Discontinuation of Any Study Drug	0	0	0	0
TEAE Leading to Dose Modifications of Study Drug	4	3	1	4

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: Participants				
Any TEAE	5	10	10	10
TEAE Related to Any Study Drug	5	10	9	10
CTCAE Grade 3-4 TEAE	4	8	10	6
CTCAE Grade 3-4 TEAE Related to Any Study Drug	2	7	6	5
CTCAE Grade 5 TEAE	0	0	1	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	1	0
Serious TEAE	3	6	7	5
Serious TEAE Related to Any Study Drug	1	2	3	3
TEAE Leading to Discontinuation of Any Study Drug	0	0	2	2
TEAE Leading to Dose Modifications of Study Drug	4	8	9	7

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: Participants				
Any TEAE	9	5	5	9
TEAE Related to Any Study Drug	9	5	4	3
CTCAE Grade 3-4 TEAE	9	5	4	7
CTCAE Grade 3-4 TEAE Related to Any Study Drug	7	3	3	2
CTCAE Grade 5 TEAE	0	1	1	4
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	5	2	4	7
Serious TEAE Related to Any Study Drug	3	1	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	2	1	0
TEAE Leading to Dose Modifications of Study Drug	4	3	2	0

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: Participants				
Any TEAE	2	5	5	
TEAE Related to Any Study Drug	0	3	2	
CTCAE Grade 3-4 TEAE	1	4	3	
CTCAE Grade 3-4 TEAE Related to Any Study Drug	0	1	1	
CTCAE Grade 5 TEAE	0	0	0	
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	
Serious TEAE	0	3	2	
Serious TEAE Related to Any Study Drug	0	0	0	
TEAE Leading to Discontinuation of Any Study Drug	0	1	0	
TEAE Leading to Dose Modifications of Study Drug	0	3	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) During Durvalumab Treatment

End point title	Overall Response Rate (ORR) During Durvalumab Treatment[5]

End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The

ORR is defined as the percent of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

End point type	Secondary

End point timeframe:

Up to 13 cycles (12 months)

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: Endpoints are cohort specific and do not report for all arms.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	3
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	66.7 (9.4 to 99.2)	80.0 (28.4 to 99.5)	66.7 (9.4 to 99.2)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0[6]	4
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.4 to 99.4)	33.3 (0.8 to 90.6)	(to)	50.0 (6.8 to 93.2)

Notes:

[6] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	9	10	9
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	88.9 (51.8 to 99.7)	60.0 (26.2 to 87.8)	88.9 (51.8 to 99.7)

End point values	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500	Part 2 Arm D CLL/SLL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	5	10	2
Units: percentage of participants				
number (confidence interval 95%)	50.0 (6.8 to 93.2)	0 (-99999 to 99999)	0 (-99999 to 99999)	0 (-99999 to 99999)

End point values	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m²	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	5	5	10	
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	20.0 (0.5 to 71.6)	30.0 (6.7 to 65.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate During the Entire Study

End point title	Overall Response Rate During the Entire Study

End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification) (Cheson, 2014). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The ORR is defined as the percentage of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

-99999/99999 = Not Available

End point type	Secondary

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	5	3
Units: percentage of participants				
number (confidence interval 95%)	66.7 (9.4 to 99.2)	66.7 (9.4 to 99.2)	80.0 (28.4 to 99.5)	66.7 (9.4 to 99.2)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375

				+BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	0[7]	4
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.4 to 99.4)	33.3 (0.8 to 90.6)	(to)	50.0 (6.8 to 93.2)

Notes:

[7] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	9	10	9
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	100.0 (66.4 to 100.0)	70.0 (34.8 to 93.3)	88.9 (51.8 to 99.7)

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	4	5	10
Units: percentage of participants				
number (confidence interval 95%)	30.0 (6.7 to 65.2)	50.0 (6.8 to 93.2)	0 (-99999 to 99999)	0 (-99999 to 99999)

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: percentage of participants				
number (confidence interval 95%)	0 (-99999 to 99999)	0 (-99999 to 99999)	20.0 (0.5 to 71.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Response

End point title	Time to First Response

End point description:

Time to response was calculated as the time from first dose of study drug to the first response date (CR or PR for lymphoma participants and CR, CRi, nPR, PR, or PRL for CLL participants).

End point type	Secondary

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	2
Units: weeks				
median (full range (min-max))	70.85 (12.1 to 129.6)	12.60 (12.1 to 13.1)	18.20 (11.3 to 36.1)	11.85 (11.4 to 12.3)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	0[8]	2
Units: weeks				
median (full range (min-max))	13.40 (12.4 to 52.9)	13.00 (13.0 to 13.0)	(to)	13.10 (12.1 to 14.1)

Notes:

[8] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[9]	9	7	8
Units: weeks				
median (full range (min-max))	(to)	12.10 (10.9 to 72.9)	12.10 (6.6 to 26.4)	12.35 (10.3 to 15.3)

Notes:

[9] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0[10]	0[11]
Units: weeks				
median (full range (min-max))	12.00 (8.7 to 12.1)	12.10 (12.1 to 12.1)	(to)	(to)

Notes:

[10] - Unable to calculate due to insufficient number of events.

[11] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[12]	0[13]	1	
Units: weeks				
median (full range (min-max))	(to)	(to)	13.10 (13.1 to 13.1)	

Notes:

[12] - Unable to calculate due to insufficient number of events.

[13] - Unable to calculate due to insufficient number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Kaplan-Meier Estimate of Duration of response

End point title	Kaplan-Meier Estimate of Duration of response

End point description:

Duration of response is defined for responders only as the time from the first documented response (CR or PR for lymphoma participants or CR, CRi, nPR, PR, or PRL for CLL participants) to disease progression or death (from any cause). For participants with response but no progression, or death, duration of response was censored at the last date that the participant was known to be progression-free.

-99999/99999 = Not Available

End point type	Secondary

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	2
Units: weeks				
median (confidence interval 95%)	10.14 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	1	0[14]	2
Units: weeks				

median (confidence interval 95%)	99999 (-99999 to 99999)	29.29 (-99999 to 99999)	(to)	99999 (-99999 to 99999)

Notes:

[14] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	9	7	8
Units: weeks				
median (confidence interval 95%)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Notes:

[15] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0[16]	0[17]
Units: weeks				
median (confidence interval 95%)	24.14 (9.14 to 26.14)	99999 (-99999 to 99999)	(to)	(to)

Notes:

[16] - Unable to calculate due to insufficient number of events.

[17] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[18]	0[19]	1	
Units: weeks				
median (confidence interval 95%)	(to)	(to)	11.14 (-99999 to 99999)	

Notes:

[18] - Unable to calculate due to insufficient number of events.

[19] - Unable to calculate due to insufficient number of events.

Statistical analyses

No statistical analyses for this end point

Secondary: Kaplan-Meier Estimate of Progression-free Survival (PFS)

End point title	Kaplan-Meier Estimate of Progression-free Survival (PFS)

End point description:

Progression-free survival was calculated as the time from first dose of study drug to the first documented progression or death (from any cause) during the entire efficacy evaluation period. For participants with no progression or death, PFS was censored at the last assessment date the participant was known to be progression-free.

-99999/99999 = Not Available

End point type	Secondary

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: months				
median (confidence interval 95%)	8.41 (5.09 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: months				
median (confidence interval 95%)	28.71 (4.50 to 99999)	9.69 (1.64 to 12.68)	1.25 (-99999 to 99999)	3.82 (1.25 to 99999)

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: months				
median (confidence interval 95%)	2.48 (0.49 to 5.91)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	14.65 (5.75 to 14.65)

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: months				
median (confidence interval 95%)	2.06 (0.76 to 8.28)	99999 (-99999 to 99999)	1.68 (0.69 to 4.63)	1.17 (0.26 to 3.19)

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: months				
median (confidence interval 95%)	2.76 (2.50 to 3.02)	2.33 (0.79 to 10.02)	2.66 (2.56 to 5.98)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Durvalumab

End point title	Maximum Observed Plasma Concentration (Cmax) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: µg/L				
geometric mean (geometric coefficient of variation)	420264.066 (± 22.7)	361906.229 (± 30.1)	331572.478 (± 33.4)	392663.668 (± 41.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab

End point title	Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: days*µg/L				
geometric mean (geometric coefficient of variation)	4867431.378 (± 23.3)	5818262.846 (± 42.1)	4762968.345 (± 71.0)	5593532.553 (± 53.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Plasma Concentration (Tmax) of Durvalumab

End point title	Time to Maximum Plasma Concentration (Tmax) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: days				
median (full range (min-max))	0.0510 (0.042 to 1.035)	0.0479 (0.041 to 1.061)	0.0510 (0.042 to 6.788)	0.0420 (0.038 to 1.986)

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	26
Units: days*µg/L				
geometric mean (geometric coefficient of variation)	3120149.759 (± 29.5)	3225869.344 (± 31.9)	2670168.397 (± 46.7)	3053060.746 (± 37.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination Phase Half-Life (t½) of Durvalumab

End point title	Terminal Elimination Phase Half-Life (t½) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy	Arm A: Durvalumab + Lenalidomide Â± Rituximab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	27	38	25	14
Units: days				
geometric mean (geometric coefficient of variation)	17.344 (± 47.3)	16.327 (± 57.4)	15.399 (± 53.5)	11.596 (± 46.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Volume of Distribution (Vz) of Durvalumab

End point title	Volume of Distribution (Vz) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: liters				
geometric mean (geometric coefficient of variation)	5.155 (± 41.9)	6.451 (± 38.3)	7.418 (± 33.7)	5.957 (± 33.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Lenalidomide

End point title	Maximum Observed Plasma Concentration (Cmax) of Lenalidomide

End point description:

99999 = NA

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

End point values	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1	141.881 (± 22.0)	309.917 (± 6.9)		
Cycle 1 Day 15	107.635 (± 40.9)	174.090 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Clearance (CL) of Durvalumab

End point title	Clearance (CL) of Durvalumab

End point description:

End point type	Secondary

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

End point values	Arm A: Durvalumab + Lenalidomide ± Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine ± Rituximab	Arm D: Durvalumab Monotherapy
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	14	27	38	25
Units: L/day				
geometric mean (geometric coefficient of variation)	0.3082 (± 23.3)	0.2578 (± 42.1)	0.3149 (± 71.0)	0.2682 (± 53.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) of Ibrutinib

End point title	Maximum Observed Plasma Concentration (Cmax) of Ibrutinib

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

End point values	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1	129.704 (± 98.0)	67.728 (± 197.9)		
Cycle 1 Day 15	86.840 (± 136.9)	72.436 (± 166.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

End point values	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	789.297 (± 84.3)	805.299 (± 56.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide

End point title	Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

End point values	Arm A: Lenalidomide 10 mg	Arm A: Lenalidomide 20 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	4		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1	1.9500 (1.000 to 3.917)	1.1667 (1.000 to 1.433)		
Cycle 1 Day 15	3.0333 (1.233 to 4.000)	1.000 (1.000 to 1.000)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib

End point title	Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

End point values	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	586.396 (± 117.2)	436.855 (± 246.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib

End point title	Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

End point values	Arm B: Ibrutinib 420 mg	Arm B: Ibrutinib 560 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	13		
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1	2.000 (0.000 to 4.367)	1.9333 (0.933 to 3.917)		
Cycle 1 Day 15	1.8833 (1.000 to 4.000)	2.000 (1.000 to 4.083)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-L1) Concentration

End point title	Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-L1) Concentration

End point description:

Change from baseline in sPD-L1 could not be calculated as all post-baseline samples were below the lower limit of quantification (<15.60 pg/mL).

End point type	Secondary

End point timeframe:

Baseline (Cycle 1 Day 1 predose) and Day 1 of Cycles 2 to 13

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[20]	0[21]	0[22]	0[23]
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[20] - Unable to calculate due to insufficient number of events.

[21] - Unable to calculate due to insufficient number of events.

[22] - Unable to calculate due to insufficient number of events.

[23] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[24]	0[25]	0[26]	0[27]
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[24] - Unable to calculate due to insufficient number of events.

[25] - Unable to calculate due to insufficient number of events.

[26] - Unable to calculate due to insufficient number of events.

[27] - Unable to calculate due to insufficient number of events.

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[28]	0[29]	0[30]	0[31]
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[28] - Unable to calculate due to insufficient number of events.

[29] - Unable to calculate due to insufficient number of events.

[30] - Unable to calculate due to insufficient number of events.

[31] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[32]	0[33]	0[34]	0[35]
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[32] - Unable to calculate due to insufficient number of events.

[33] - Unable to calculate due to insufficient number of events.

[34] - Unable to calculate due to insufficient number of events.

[35] - Unable to calculate due to insufficient number of events.

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[36]	0[37]	0[38]	
Units: pg/mL				
arithmetic mean (standard deviation)	()	()	()	

Notes:

[36] - Unable to calculate due to insufficient number of events.

[37] - Unable to calculate due to insufficient number of events.

[38] - Unable to calculate due to insufficient number of events.

Statistical analyses

No statistical analyses for this end point

Post-hoc: Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection

End point title	Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection

End point description:

TEAEs defined as AEs occurring or worsening on or after first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. Intensity of AEs graded according to the NCI CTCAE V. 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5). This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date (assessments made until August 21, 2022).

End point type	Post-hoc

End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the study completion date of August 21, 2022 (up to approximately 75 months).

End point values	Part 1 Arm A: DUR 1500 + LEN 20	Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375	Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375	Part 1 Arm B: DUR 1500 + IBR 420
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	8	3
Units: Participants				
Any TEAE	3	3	8	3
TEAE Related to Any Study Drug	3	3	8	3
CTCAE Grade 3-4 TEAE	1	3	7	2
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	3	7	1
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	1	2	4	2
Serious TEAE Related to Any Study Drug	1	2	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	0	3	1
TEAE Leading to Dose Modifications of Study Drug	1	3	5	3

End point values	Part 1 Arm B: DUR 1500 + IBR 560	Part 1 Arm C: DUR 1500 + RIT 375	Part 1 Arm C: DUR 1500 + BEN 70	Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	1	4
Units: Participants				
Any TEAE	4	3	1	4
TEAE Related to Any Study Drug	4	3	0	4
CTCAE Grade 3-4 TEAE	4	2	1	3
CTCAE Grade 3-4 TEAE Related to Any Study Drug	1	2	0	2
CTCAE Grade 5 TEAE	0	0	0	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	3	2	1	1
Serious TEAE Related to Any Study Drug	0	1	0	0
TEAE Leading to Discontinuation of Any Study Drug	0	0	0	0
TEAE Leading to Dose Modifications of Study Drug	4	3	1	4

End point values	Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90	Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420	Part 2 Arm B MCL: DUR 1500 + IBR 560	Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	10	10
Units: Participants				
Any TEAE	5	10	10	10
TEAE Related to Any Study Drug	5	10	9	10
CTCAE Grade 3-4 TEAE	4	9	10	6
CTCAE Grade 3-4 TEAE Related to Any Study Drug	2	8	6	5
CTCAE Grade 5 TEAE	0	0	1	0
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	1	0
Serious TEAE	3	6	7	5
Serious TEAE Related to Any Study Drug	1	3	3	3
TEAE Leading to Discontinuation of Any Study Drug	0	0	2	2
TEAE Leading to Dose Modifications of Study Drug	4	9	9	7

End point values	Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70	Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70	Part 2 Arm D FL: DUR 1500	Part 2 Arm D DLBCL: DUR 1500

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	5	5	10
Units: Participants				
Any TEAE	9	5	5	9
TEAE Related to Any Study Drug	9	5	4	3
CTCAE Grade 3-4 TEAE	9	5	4	7
CTCAE Grade 3-4 TEAE Related to Any Study Drug	7	3	3	2
CTCAE Grade 5 TEAE	0	1	1	4
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	0
Serious TEAE	5	2	4	7
Serious TEAE Related to Any Study Drug	3	1	3	1
TEAE Leading to Discontinuation of Any Study Drug	1	2	1	0
TEAE Leading to Dose Modifications of Study Drug	4	3	2	0

End point values	Part 2 Arm D CLL/SLL: DUR 1500	Part 2 Arm D MCL: DUR 1500	Part 2 Arm D HL: DUR 1500	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	5	5	
Units: Participants				
Any TEAE	2	5	5	
TEAE Related to Any Study Drug	0	3	2	
CTCAE Grade 3-4 TEAE	1	4	3	
CTCAE Grade 3-4 TEAE Related to Any Study Drug	0	1	1	
CTCAE Grade 5 TEAE	0	0	0	
CTCAE Grade 5 TEAE Related to Any Study Drug	0	0	0	
Serious TEAE	0	3	2	
Serious TEAE Related to Any Study Drug	0	0	0	
TEAE Leading to Discontinuation of Any Study Drug	0	1	0	
TEAE Leading to Dose Modifications of Study Drug	0	3	3	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs assessed from first dose to 90 days from last dose of durva or 28 days from last dose of lenalidomide, ibrutinib, rituximab, bendamustine, or IFRT, whichever occurs later (up to approximately 75 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Arm A: Durvalumab + Lenalidomide + Rituximab
Reporting group description: Durvalumab + Lenalidomide + Rituximab	
Reporting group title	Arm B: Durvalumab + Ibrutinib
Reporting group description: Durvalumab + Ibrutinib	
Reporting group title	Arm C: Durvalumab + Bendamustine + Rituximab
Reporting group description: Durvalumab + Bendamustine + Rituximab	
Reporting group title	Dura mono to Durvalumab + Bendamustine + Rituximab
Reporting group description: Durvalumab monotherapy to Durvalumab + Bendamustine + Rituximab	
Reporting group title	Dura mono to Durvalumab + Lenalidomide + Rituximab
Reporting group description: Durvalumab monotherapy to Durvalumab + Lenalidomide + Rituximab	
Reporting group title	Dura mono to Durvalumab + Ibrutinib
Reporting group description: Durvalumab monotherapy to Durvalumab + Ibrutinib	
Reporting group title	Arm D: Durvalumab Monotherapy
Reporting group description: Durvalumab Monotherapy	

Serious adverse events	Arm A: Durvalumab + Lenalidomide + Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine + Rituximab
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 14 (50.00%)	18 / 27 (66.67%)	19 / 38 (50.00%)
number of deaths (all causes)	4	6	21
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			

subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Organising pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
General physical condition abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
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 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (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
Syncope			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (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
Pancytopenia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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	2 / 14 (14.29%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	2 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Aptyalism			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Haematemesis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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 perforation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Hepatitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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			
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
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			
Bronchiolitis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (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
Bronchitis viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Lung infection			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (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
Vascular device infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 14 (14.29%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dura mono to Durvalumab + Bendamustine + Rituximab	Dura mono to Durvalumab + Lenalidomide + Rituximab	Dura mono to Durvalumab + Ibrutinib
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
number of deaths (all causes)	3	5	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Squamous cell carcinoma of lung			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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

Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Organising pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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

Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
General physical condition abnormal			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (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
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Post procedural haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Cytopenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Colon dysplasia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (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
Aptyalism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Gastric haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Hepatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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			
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Bronchitis viral			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Pleural infection bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Neutropenic sepsis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 device infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Streptococcal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (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	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm D: Durvalumab Monotherapy		
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 27 (59.26%)		
number of deaths (all causes)	12		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypotension			

subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Jugular vein thrombosis				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Superior vena cava syndrome				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	4 / 27 (14.81%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pain				

subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	3 / 27 (11.11%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Cytokine release syndrome				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	2 / 27 (7.41%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Organising pneumonia				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Investigations			
General physical condition abnormal			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Atrial fibrillation			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute coronary syndrome			

subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytopenia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			

subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon dysplasia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aptyalism			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric haemorrhage			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal perforation			

subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Rectal haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal haemorrhage			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			

subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pleural infection bacterial				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection viral				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular device infection				

subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal infection			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Arm A: Durvalumab + Lenalidomide + Rituximab	Arm B: Durvalumab + Ibrutinib	Arm C: Durvalumab + Bendamustine + Rituximab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	27 / 27 (100.00%)	37 / 38 (97.37%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	4 / 27 (14.81%)	2 / 38 (5.26%)
occurrences (all)	0	5	2
Venous thrombosis limb			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 14 (7.14%)	4 / 27 (14.81%)	5 / 38 (13.16%)
occurrences (all)	1	4	5
Mucosal inflammation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Early satiety			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	6 / 14 (42.86%)	6 / 27 (22.22%)	12 / 38 (31.58%)
occurrences (all)	8	7	13

General physical health deterioration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	2 / 38 (5.26%)
occurrences (all)	0	2	2
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Chills			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Non-cardiac chest pain			
subjects affected / exposed	2 / 14 (14.29%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	2	2	1
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	3 / 27 (11.11%)	3 / 38 (7.89%)
occurrences (all)	2	3	3
Pain			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	1	2	1
Pyrexia			
subjects affected / exposed	4 / 14 (28.57%)	6 / 27 (22.22%)	13 / 38 (34.21%)
occurrences (all)	4	12	15
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Immunodeficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	2 / 14 (14.29%)	6 / 27 (22.22%)	10 / 38 (26.32%)
occurrences (all)	2	8	11
Dyspnoea			
subjects affected / exposed	4 / 14 (28.57%)	2 / 27 (7.41%)	6 / 38 (15.79%)
occurrences (all)	5	4	7
Epistaxis			
subjects affected / exposed	0 / 14 (0.00%)	4 / 27 (14.81%)	1 / 38 (2.63%)
occurrences (all)	0	4	1
Hypoxia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Laryngeal inflammation			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Tachypnoea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Sinus pain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	2	1	1
Sinus congestion			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	1	2	0
Productive cough			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	1	1	2
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	2 / 38 (5.26%)
occurrences (all)	1	4	2
Oropharyngeal pain			
subjects affected / exposed	2 / 14 (14.29%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	2	2	1

Sinus disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Depression			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Apathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	3 / 38 (7.89%)
occurrences (all)	0	2	3
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	2 / 38 (5.26%)
occurrences (all)	0	3	2
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	1	1	2
Lymphocyte count decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	3	0	3
Lipase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	3
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 14 (7.14%)	4 / 27 (14.81%)	3 / 38 (7.89%)
occurrences (all)	1	4	3
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	1	1	2
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 14 (14.29%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	2	1	3
White blood cell count decreased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	6	0	1
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	3 / 38 (7.89%)
occurrences (all)	2	1	3
Platelet count decreased			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	3	2	3
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	5 / 27 (18.52%)	1 / 38 (2.63%)
occurrences (all)	0	5	1
Fall			
subjects affected / exposed	0 / 14 (0.00%)	4 / 27 (14.81%)	0 / 38 (0.00%)
occurrences (all)	0	5	0
Infusion related reaction			

subjects affected / exposed	2 / 14 (14.29%)	0 / 27 (0.00%)	5 / 38 (13.16%)
occurrences (all)	3	0	6
Ligament sprain			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	1	2	0
Overdose			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	2	0	1
Wound			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Epidermolysis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	0	4	1
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	4 / 27 (14.81%)	0 / 38 (0.00%)
occurrences (all)	0	4	0
Pericardial disease			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	2 / 38 (5.26%)
occurrences (all)	1	3	3
Aphasia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 14 (14.29%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	3	2	1
Tremor			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 14 (21.43%)	4 / 27 (14.81%)	4 / 38 (10.53%)
occurrences (all)	4	4	6
Dysgeusia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	2	1	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 14 (35.71%)	5 / 27 (18.52%)	11 / 38 (28.95%)
occurrences (all)	6	8	21
Eosinophilia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Febrile neutropenia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	3
Haemolytic anaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	3 / 14 (21.43%)	1 / 27 (3.70%)	3 / 38 (7.89%)
occurrences (all)	3	1	6
Neutropenia			
subjects affected / exposed	6 / 14 (42.86%)	9 / 27 (33.33%)	14 / 38 (36.84%)
occurrences (all)	16	22	22
Pancytopenia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	3 / 14 (21.43%)	8 / 27 (29.63%)	12 / 38 (31.58%)
occurrences (all)	4	11	19
Leukopenia			
subjects affected / exposed	3 / 14 (21.43%)	3 / 27 (11.11%)	5 / 38 (13.16%)
occurrences (all)	7	4	9
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Ear discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0

Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	2	2
Conjunctival haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	3 / 38 (7.89%)
occurrences (all)	0	3	3
Retinopathy hypertensive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	8 / 14 (57.14%)	6 / 27 (22.22%)	7 / 38 (18.42%)
occurrences (all)	14	6	7
Abdominal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Abdominal distension			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	2 / 14 (14.29%)	4 / 27 (14.81%)	7 / 38 (18.42%)
occurrences (all)	2	6	9
Abdominal pain upper			
subjects affected / exposed	2 / 14 (14.29%)	4 / 27 (14.81%)	1 / 38 (2.63%)
occurrences (all)	3	5	1
Diarrhoea			
subjects affected / exposed	4 / 14 (28.57%)	15 / 27 (55.56%)	7 / 38 (18.42%)
occurrences (all)	5	27	11
Dry mouth			

subjects affected / exposed	1 / 14 (7.14%)	4 / 27 (14.81%)	1 / 38 (2.63%)
occurrences (all)	1	4	1
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	2 / 14 (14.29%)	5 / 27 (18.52%)	12 / 38 (31.58%)
occurrences (all)	2	5	13
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	2 / 38 (5.26%)
occurrences (all)	1	3	2
Gingival pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	3 / 38 (7.89%)
occurrences (all)	0	0	3
Rectal haemorrhage			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Stomatitis			

subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Vomiting			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	4 / 38 (10.53%)
occurrences (all)	1	3	7
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Hepatocellular injury			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 14 (14.29%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	3	3	2
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	4 / 27 (14.81%)	0 / 38 (0.00%)
occurrences (all)	0	5	0
Skin fissures			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	3 / 14 (21.43%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	9	3	0
Rash			

subjects affected / exposed	0 / 14 (0.00%)	11 / 27 (40.74%)	4 / 38 (10.53%)
occurrences (all)	0	13	5
Pruritus			
subjects affected / exposed	3 / 14 (21.43%)	3 / 27 (11.11%)	5 / 38 (13.16%)
occurrences (all)	3	3	5
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	5	1
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	5 / 27 (18.52%)	1 / 38 (2.63%)
occurrences (all)	0	5	1
Ecchymosis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Dysuria			
subjects affected / exposed	1 / 14 (7.14%)	4 / 27 (14.81%)	1 / 38 (2.63%)
occurrences (all)	1	4	1
Haematuria			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	1	5	0
Micturition urgency			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	2 / 14 (14.29%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	2	1	1
Endocrine disorders			
Hypothyroidism			

subjects affected / exposed	2 / 14 (14.29%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	2	2	0
Hyperthyroidism			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Thyroiditis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	2 / 14 (14.29%)	1 / 27 (3.70%)	3 / 38 (7.89%)
occurrences (all)	2	1	6
Arthralgia			
subjects affected / exposed	1 / 14 (7.14%)	7 / 27 (25.93%)	1 / 38 (2.63%)
occurrences (all)	1	11	1
Flank pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Muscular weakness			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Muscle spasms			
subjects affected / exposed	3 / 14 (21.43%)	9 / 27 (33.33%)	0 / 38 (0.00%)
occurrences (all)	3	11	0
Muscle discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc degeneration			

subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Periarthritis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Neck pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	5 / 14 (35.71%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	5	4	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	2	2	0
Bronchiolitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2

Bronchitis			
subjects affected / exposed	1 / 14 (7.14%)	6 / 27 (22.22%)	5 / 38 (13.16%)
occurrences (all)	1	10	7
Cytomegalovirus infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Gastroenteritis viral			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Herpes zoster			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	0	1	2
Nasopharyngitis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	3 / 38 (7.89%)
occurrences (all)	1	2	3
Laryngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	3	2	0
Lung infection			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	0	4	1
Metapneumovirus infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	2
Oral fungal infection			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	1 / 38 (2.63%)
occurrences (all)	1	2	1
Otitis externa			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	2	0
Paronychia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	0	4	0
Tonsillitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	0 / 38 (0.00%)
occurrences (all)	0	3	0
Rhinovirus infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Skin infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	3 / 38 (7.89%)
occurrences (all)	0	0	3
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	4	0

Tooth infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	3 / 27 (11.11%)	2 / 38 (5.26%)
occurrences (all)	1	3	2
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	5 / 27 (18.52%)	2 / 38 (5.26%)
occurrences (all)	1	8	3
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 27 (3.70%)	2 / 38 (5.26%)
occurrences (all)	2	1	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	3 / 27 (11.11%)	1 / 38 (2.63%)
occurrences (all)	0	3	1
Hyperkalaemia			
subjects affected / exposed	1 / 14 (7.14%)	2 / 27 (7.41%)	0 / 38 (0.00%)
occurrences (all)	3	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	3 / 38 (7.89%)
occurrences (all)	0	0	6
Hypokalaemia			
subjects affected / exposed	2 / 14 (14.29%)	2 / 27 (7.41%)	1 / 38 (2.63%)
occurrences (all)	6	5	1
Decreased appetite			
subjects affected / exposed	5 / 14 (35.71%)	1 / 27 (3.70%)	7 / 38 (18.42%)
occurrences (all)	6	1	7
Dehydration			

subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	2 / 38 (5.26%)
occurrences (all)	0	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 27 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 27 (3.70%)	0 / 38 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Dura mono to Durvalumab + Bendamustine + Rituximab	Dura mono to Durvalumab + Lenalidomide + Rituximab	Dura mono to Durvalumab + Ibrutinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	6 / 7 (85.71%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Mucosal inflammation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	2 / 3 (66.67%)
occurrences (all)	2	2	2
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Immunodeficiency			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Laryngeal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Apathy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immunoglobulins decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Platelet count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Congenital, familial and genetic disorders			
Epidermolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial disease			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eosinophilia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemolytic anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	3 / 3 (100.00%)
occurrences (all)	0	2	5
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	3 / 3 (100.00%)
occurrences (all)	1	1	7
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tinnitus			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinopathy hypertensive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 3 (66.67%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatocellular injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle discomfort			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Periarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lip infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hypocalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	1	3
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			

subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	2	1	1
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 3 (33.33%)
occurrences (all)	0	1	1

Non-serious adverse events	Arm D: Durvalumab Monotherapy		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 27 (92.59%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Venous thrombosis limb			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	3 / 27 (11.11%)		
occurrences (all)	4		
General disorders and administration site conditions			

Asthenia				
subjects affected / exposed	9 / 27 (33.33%)			
occurrences (all)	11			
Mucosal inflammation				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Early satiety				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
General physical health deterioration				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Influenza like illness				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Chills				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Non-cardiac chest pain				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	5 / 27 (18.52%)			
occurrences (all)	6			
Pain				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Pyrexia				
subjects affected / exposed	13 / 27 (48.15%)			
occurrences (all)	19			

Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Immunodeficiency			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 27 (18.52%)		
occurrences (all)	5		
Dyspnoea			
subjects affected / exposed	6 / 27 (22.22%)		
occurrences (all)	7		
Epistaxis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Laryngeal inflammation			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Sinus pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		

Sinus congestion subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Productive cough subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Pleural effusion subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Sinus disorder subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Depression subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Confusional state subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Apathy subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Insomnia subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 3		
Investigations Blood bilirubin increased subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Blood alkaline phosphatase increased			

subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Lipase increased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Immunoglobulins decreased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Alanine aminotransferase increased				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Aspartate aminotransferase increased				
subjects affected / exposed	2 / 27 (7.41%)			
occurrences (all)	2			
White blood cell count decreased				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Weight decreased				

subjects affected / exposed	4 / 27 (14.81%)		
occurrences (all)	4		
Platelet count decreased			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Infusion related reaction			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Overdose			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Epidermolysis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Palpitations			

subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Pericardial disease			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Aphasia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		

Dysgeusia			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 27 (29.63%)		
occurrences (all)	17		
Eosinophilia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Febrile neutropenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Haemolytic anaemia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	6 / 27 (22.22%)		
occurrences (all)	13		
Pancytopenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	9 / 27 (33.33%)		
occurrences (all)	11		
Leukopenia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypoacusis			

subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Ear discomfort			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Conjunctival haemorrhage			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Retinopathy hypertensive			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Abdominal discomfort			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Abdominal distension			

subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Abdominal pain				
subjects affected / exposed	3 / 27 (11.11%)			
occurrences (all)	4			
Abdominal pain upper				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	5 / 27 (18.52%)			
occurrences (all)	6			
Dry mouth				
subjects affected / exposed	2 / 27 (7.41%)			
occurrences (all)	2			
Dyspepsia				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Dysphagia				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	2 / 27 (7.41%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	4 / 27 (14.81%)			
occurrences (all)	5			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Gingival pain				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Mouth ulceration				

subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Oral pain subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Stomatitis subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Vomiting subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 3		
Hepatobiliary disorders Hepatitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Hepatocellular injury subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Dermatitis exfoliative generalised subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Dermatitis acneiform subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Urticaria			

subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Skin fissures			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	5 / 27 (18.52%)		
occurrences (all)	5		
Pruritus			
subjects affected / exposed	3 / 27 (11.11%)		
occurrences (all)	3		
Night sweats			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		

Haematuria			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hyperthyroidism			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Thyroiditis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Arthralgia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Muscle spasms			

subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Muscle discomfort				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Intervertebral disc degeneration				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Groin pain				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Musculoskeletal discomfort				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Periarthritis				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Pain in jaw				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Pain in extremity				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Neck pain				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				

subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Cytomegalovirus infection			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	1 / 27 (3.70%)		
occurrences (all)	1		
Gastroenteritis viral			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	2 / 27 (7.41%)		
occurrences (all)	2		
Laryngitis			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Lip infection			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		

Lower respiratory tract infection				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Lung infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Metapneumovirus infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Oral fungal infection				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			
Tonsillitis				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 27 (0.00%)			
occurrences (all)	0			
Rhinovirus infection				
subjects affected / exposed	1 / 27 (3.70%)			
occurrences (all)	1			

Sinusitis subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Skin infection subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Respiratory tract infection subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Tooth infection subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 27 (3.70%) 1		
Viral infection subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Metabolism and nutrition disorders Hypocalcaemia subjects affected / exposed occurrences (all)	3 / 27 (11.11%) 3		
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2		
Hyperuricaemia subjects affected / exposed occurrences (all)	2 / 27 (7.41%) 2		
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 27 (0.00%) 0		
Hyperglycaemia			

subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	5 / 27 (18.52%)		
occurrences (all)	5		
Decreased appetite			
subjects affected / exposed	7 / 27 (25.93%)		
occurrences (all)	8		
Dehydration			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 27 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	3 / 27 (11.11%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 May 2017	Addition of 2 new dose levels (ie, dose levels -2 and -3) to the Arm A dose finding part
14 December 2017	Discontinuation of Arm A to the enrollment of new participants
12 September 2019	Discontinuation of Follow-up Period, assessments and data collection
22 April 2020	Participants will move to a tablet formulation when the capsule formulation is no longer commercially available. For participants continuing on ibrutinib, scheduled clinic visits will be done according to standard of care per investigator's discretion.

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.

Study placed on full clinical hold by US FDA on 05Sep2017. Study closed for further enrollment and subjects discontinued from all treatments. Subjects followed for SPMs for 5 years after last subject was enrolled per protocol

Notes: