

**Clinical trial results:****A Phase Ib/II Study Evaluating the Safety and Efficacy of Obinutuzumab in Combination With Idasanutlin in Patients With Relapsed or Refractory Follicular Lymphoma and Obinutuzumab or Rituximab in Combination with Idasanutlin in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma****Summary**

EudraCT number	2015-002100-83
Trial protocol	DE
Global end of trial date	20 May 2019

Results information

Result version number	v1 (current)
This version publication date	15 May 2020
First version publication date	15 May 2020

Trial information**Trial identification**

Sponsor protocol code	BH29812
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02624986
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche, Ltd.
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., +41 616878333, global.trial_information@roche.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 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 May 2019
Global end of trial reached?	Yes
Global end of trial date	20 May 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary safety objective was to determine the recommended Phase II dose (RP2D) for idasanutlin when given in combination with a fixed dose of obinutuzumab or rituximab on the basis of the incidence of dose-limiting toxicities.

The primary efficacy objective for this study is to evaluate the efficacy of obinutuzumab in combination with idasanutlin in relapsed/refractory (R/R) follicular lymphoma (FL) and rituximab in combination with idasanutlin in R/R diffuse large B-cell lymphoma (DLBCL).

Protection of trial subjects:

This study was conducted in full conformance with the ICH E6 guideline for GCP and the principles of the Declaration of Helsinki, or the laws and regulations of the country in which the research is conducted, whichever afforded the greater protection to the individual. All study subjects were required to read and sign an informed consent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 December 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 6
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	New Zealand: 3
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	25
EEA total number of subjects	5

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)	18
From 65 to 84 years	6
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 45 patients were screened, twenty-five of whom were enrolled in the dose escalation phase. The sponsor decided to terminate the study early and the expansion phase was not opened.

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	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg

Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 100 milligrams (mg) was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered intravenously (IV) on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Arm title	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
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Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered IV on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 150 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Arm title	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
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Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 200 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F16-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 200 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered IV on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Arm title	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
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Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 150 mg orally in combination with rituximab 375 milligrams per square meter of body surface area (mg/m²) IV for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
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Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 150 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

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

Dosage and administration details:

Rituximab 375 mg per square metre of body surface area (mg/m²) was administered IV on Day 1 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Arm title	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²
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Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 200 mg orally in combination with rituximab 375 mg/m² IV for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F16-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 200 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

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

Dosage and administration details:

Rituximab 375 mg/m² was administered IV on Day 1 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with DLBCL who achieved a complete response according to modified Lugano 2014 criteria at the end of induction were allowed to proceed to hematopoietic stem cell transplantation if deemed appropriate by the investigator.

Arm title	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
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Arm description:

Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
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Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 100 milligrams (mg) was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered IV on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab 1000 mg IV once every 2 months until disease progression or unacceptable toxicity for up to 2 years.

Arm title	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Arm description:

Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Arm type	Experimental
Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 150 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle for up to 6 cycles of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered IV on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab 1000 mg IV once every 2 months until disease progression or unacceptable toxicity for up to 2 years.

Arm title	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Arm description:

Participants with relapsed/refractory follicular lymphoma (FL) in this bridging cohort received induction treatment with single-agent obinutuzumab 1000 mg IV for Cycle 1 and then idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for Cycles 2-6 (1 cycle = 28 days).

Arm type	Experimental
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Investigational medicinal product name	Idasanutlin
Investigational medicinal product code	RO5503781/F17-01
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Idasanutlin 150 mg was taken orally once per day on Days 1 to 5 of each 28-day cycle starting at Cycle 2 for up to 5 cycles of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab.

Investigational medicinal product name	Obinutuzumab
Investigational medicinal product code	RO5072759/F06-01
Other name	Gazyvaro
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

A flat dose of obinutuzumab 1000 mg was administered IV on Days 1, 8, and 15 of Cycle 1 and Day 1 of Cycles 2 to 6 (1 cycle was 28 days) of induction treatment. Participants with FL who achieved a complete response or partial response according to modified Lugano 2014 criteria at the end of induction were to receive maintenance treatment with obinutuzumab 1000 mg IV once every 2 months until disease progression or unacceptable toxicity for up to 2 years.

Number of subjects in period 1	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Started	2	3	2
Received Any Study Treatment	1	3	2
Completed	0	0	0
Not completed	2	3	2
Consent withdrawn by subject	-	-	-
Death	-	1	2
Progressive Disease	-	1	-
Study Terminated by Sponsor	1	1	-
Protocol deviation	1	-	-

Number of subjects in period 1	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Started	3	4	2
Received Any Study Treatment	3	4	2
Completed	0	0	0
Not completed	3	4	2
Consent withdrawn by subject	-	-	-
Death	2	2	-
Progressive Disease	-	-	-
Study Terminated by Sponsor	1	2	2

Protocol deviation	-	-	-
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Number of subjects in period 1	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Started	4	5
Received Any Study Treatment	4	5
Completed	0	0
Not completed	4	5
Consent withdrawn by subject	-	1
Death	-	1
Progressive Disease	-	-
Study Terminated by Sponsor	4	3
Protocol deviation	-	-

Baseline characteristics

Reporting groups

Reporting group title	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).	
Reporting group title	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).	
Reporting group title	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 200 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).	
Reporting group title	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Reporting group description: Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 150 mg orally in combination with rituximab 375 milligrams per square meter of body surface area (mg/m ²) IV for 6 cycles (1 cycle = 28 days).	
Reporting group title	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²
Reporting group description: Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 200 mg orally in combination with rituximab 375 mg/m ² IV for 6 cycles (1 cycle = 28 days).	
Reporting group title	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).	
Reporting group title	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).	
Reporting group title	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description: Participants with relapsed/refractory follicular lymphoma (FL) in this bridging cohort received induction treatment with single-agent obinutuzumab 1000 mg IV for Cycle 1 and then idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for Cycles 2-6 (1 cycle = 28 days).	

Reporting group values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Number of subjects	2	3	2

Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1	1	2
From 65-84 years	1	1	0
85 years and over	0	1	0
Age Continuous Units: Years			
arithmetic mean	62.5	70.7	55.5
standard deviation	± 6.4	± 15.2	± 10.6
Sex: Female, Male Units: Participants			
Female	1	1	1
Male	1	2	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	3	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	2
Unknown or Not Reported	0	0	0

Reporting group values	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Number of subjects	3	4	2
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	3	2
From 65-84 years	1	1	0

85 years and over	0	0	0
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Age Continuous Units: Years arithmetic mean standard deviation	67.3 ± 8.4	56.5 ± 12.9	52.5 ± 6.4
Sex: Female, Male Units: Participants			
Female	1	2	0
Male	2	2	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	2	3	1
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	2	3	2
Unknown or Not Reported	0	1	0

Reporting group values	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	Total
Number of subjects	4	5	25
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	3	18
From 65-84 years	0	2	6
85 years and over	0	0	1
Age Continuous Units: Years arithmetic mean standard deviation	53.3 ± 6.7	64.2 ± 9.8	-
Sex: Female, Male Units: Participants			
Female	2	4	12
Male	2	1	13

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	0	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	5	17
More than one race	1	0	1
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	4	5	23
Unknown or Not Reported	0	0	1

End points

End points reporting groups

Reporting group title	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).
Reporting group title	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).
Reporting group title	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 200 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).
Reporting group title	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Reporting group description:	Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 150 mg orally in combination with rituximab 375 milligrams per square meter of body surface area (mg/m ²) IV for 6 cycles (1 cycle = 28 days).
Reporting group title	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²
Reporting group description:	Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 200 mg orally in combination with rituximab 375 mg/m ² IV for 6 cycles (1 cycle = 28 days).
Reporting group title	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).
Reporting group title	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).
Reporting group title	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Reporting group description:	Participants with relapsed/refractory follicular lymphoma (FL) in this bridging cohort received induction treatment with single-agent obinutuzumab 1000 mg IV for Cycle 1 and then idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for Cycles 2-6 (1 cycle = 28 days).
Subject analysis set title	DLBCL/FL Combined: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	This is a pharmacokinetics analysis cohort of participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) who received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).
Subject analysis set title	DLBCL/FL Combined: Idasanutlin 150 mg + Obinutuzumab 1000 mg

Subject analysis set type	Sub-group analysis
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Subject analysis set description:

This is a pharmacokinetics analysis cohort of participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) who received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Subject analysis set title	DLBCL/FL: Idasanutlin 100/150/200 mg + Obinutuzumab 1000 mg
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

This is a pharmacokinetics analysis cohort of participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) who received induction treatment with idasanutlin 100 milligrams (mg), 150 mg, or 200 mg orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).

Subject analysis set title	DLBCL Combined: Idasanutlin 150/200 mg + Rituximab 375 mg/m ²
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

This is a pharmacokinetics analysis cohort of participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL) who received induction treatment with idasanutlin 150 mg or 200 mg orally in combination with rituximab 375 milligrams per square meter of body surface area (mg/m²) IV for 6 cycles (1 cycle = 28 days).

Primary: Percentage of Participants with Complete Response at the End of Induction, Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography and Computed Tomography (PET-CT) Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Participants with Complete Response at the End of Induction, Determined by an Independent Review Committee (IRC) on the Basis of Positron Emission Tomography and Computed Tomography (PET-CT) Scans Using Modified Lugano 2014 Criteria ^[1]
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End point description:

The plan was for the IRC to evaluate responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT-based complete response (CR), which required a complete metabolic response with a score of 1, 2, or 3 with or without a residual mass in lymph nodes and extralymphatic sites on the PET 5-point scale for 18-fluorodeoxyglucose (FDG) uptake (1 = no uptake above background; 2 = uptake less than or equal to [\leq] mediastinum; 3 = uptake greater than [$>$] mediastinum and \leq liver; 4 = uptake moderately $>$ liver; 5 = uptake markedly $>$ liver and/or new lesions). The CR criteria were slightly modified to require normal bone marrow by morphology (if indeterminate, immunohistochemistry negative). PET-CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were to be considered non-responders.

End point type	Primary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 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: The primary end point was to be analyzed based on responses of subjects in the dose expansion phase as evaluated by the IRC; however, there are no results to report because the dose expansion phase did not open for enrollment. The sponsor decided to terminate the study early due to the modest benefit achieved at the maximum tolerated dose during the dose escalation phase.

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[2]	0 ^[3]	0 ^[4]	0 ^[5]

Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

- [2] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [3] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [4] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [5] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[6]	0 ^[7]	0 ^[8]	0 ^[9]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

- [6] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [7] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [8] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.
 [9] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with a Dose-Limiting Toxicity

End point title	Number of Participants with a Dose-Limiting Toxicity
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End point description:

A dose-limiting toxicity (DLT) was defined as at least one of the following events occurring during Cycle 1 (or first 2 cycles in the bridging FL cohort) of treatment and assessed by the investigator as not clearly related to the underlying disease: Any Grade 5 adverse event (AE; severity graded per NCI-CTCAE v4.0) unless due to the underlying malignancy or extraneous causes; AE of any grade that leads to a delay of more than (>)14 days in the start of the next treatment cycle; Grade 3 or 4 non-hematologic AEs (with exceptions); Lab results suggestive of potential drug-induced liver injury (according to Hy's law); Grade 3 or 4 neutropenia in the presence of sustained fever of >38 C (lasting >5 days) or a documented infection; Grade 4 neutropenia or thrombocytopenia lasting >7 days; Grade 3 or 4 thrombocytopenia if associated with Grade ≥3 bleeding; Other toxicities considered clinically relevant and related to study treatment as determined by the investigator and medical monitor.

End point type	Secondary
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End point timeframe:

Cycles 1, 2 (1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: Participants				
Any DLT	0	0	2	0
Thrombocytopenia	0	0	2	0

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Participants				
Any DLT	1	0	1	1
Thrombocytopenia	1	0	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria

End point title	Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Modified Lugano 2014 Criteria
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End point description:

The investigator evaluated responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT-based complete response (CR), which required a complete metabolic response with a score of 1, 2, or 3 with or without a residual mass in lymph nodes and extralymphatic sites on the PET 5-point scale for 18-fluorodeoxyglucose (FDG) uptake (1 = no uptake above background; 2 = uptake less than or equal to [\leq] mediastinum; 3 = uptake greater than [$>$] mediastinum and \leq liver; 4 = uptake moderately $>$ liver; 5 = uptake markedly $>$ liver and/or new lesions). The CR criteria were slightly modified to require normal bone marrow by morphology (if indeterminate, immunohistochemistry negative). PET-CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were considered non-responders. Exploratory analysis of dose-escalation phase efficacy is reported.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	3
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 77.64)	33.3 (1.70 to 86.46)	0 (0.00 to 77.64)	0 (0.00 to 63.16)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 52.71)	50.0 (2.53 to 97.47)	0 (0.00 to 52.71)	40.0 (7.64 to 81.07)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Lugano 2014 Criteria

End point title	Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Lugano 2014 Criteria
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End point description:

The investigator evaluated responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT-based complete response (CR), which required a complete metabolic response with a score of 1, 2, or 3 with or without a residual mass in lymph nodes and extralymphatic sites on the PET 5-point scale for 18-fluorodeoxyglucose (FDG) uptake (1 = no uptake above background; 2 = uptake less than or equal to [\leq] mediastinum; 3 = uptake greater than [$>$] mediastinum and \leq liver; 4 = uptake moderately $>$ liver; 5 = uptake markedly $>$ liver and/or new lesions). The CR criteria for participants with bone marrow involvement at screening required no evidence of FDG-avid disease in the marrow. PET-CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were considered non-responders. Exploratory analysis of dose-escalation phase efficacy is reported.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	3
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 77.64)	33.3 (1.70 to 86.46)	0 (0.00 to 77.64)	0 (0.00 to 63.16)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 52.71)	50.0 (2.53 to 97.47)	0 (0.00 to 52.71)	40.0 (7.64 to 81.07)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Response at the End of Induction, Determined by the IRC on the Basis of CT Scans Alone Using Lugano 2014 Criteria

End point title	Percentage of Participants with Complete Response at the End of Induction, Determined by the IRC on the Basis of CT Scans Alone Using Lugano 2014 Criteria
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End point description:

The independent review committee (IRC) was to evaluate responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a computed tomography (CT)-based complete response (CR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 centimetres in the longest transverse diameter of a lesion [LDi]; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[10]	0 ^[11]	0 ^[12]	0 ^[13]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[10] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[11] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[12] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[13] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[14]	0 ^[15]	0 ^[16]	0 ^[17]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[14] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[15] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[16] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[17] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria

End point title	Percentage of Participants with Complete Response at the End of Induction, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria
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End point description:

The investigator evaluated responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a computed tomography (CT)-based complete response (CR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 centimetres in the longest transverse diameter of a lesion [LDi]; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). CT scans were performed at end of induction only on participants who had received at least 2 cycles of induction treatment; those without a post-baseline tumor assessment were to be considered non-responders. Exploratory analysis of dose-escalation phase efficacy is reported.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	2	3
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 77.64)	33.3 (1.70 to 86.46)	0 (0.00 to 77.64)	0 (0.00 to 63.16)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Percentage of participants				
number (confidence interval 90%)	0 (0.00 to 52.71)	0 (0.00 to 77.64)	0 (0.00 to 52.71)	20.0 (1.02 to 65.74)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response at the End of Induction, Determined by the IRC on the Basis of PET-CT Scans Using Lugano 2014 Criteria

End point title	Percentage of Participants with Objective Response at the End of Induction, Determined by the IRC on the Basis of PET-CT Scans Using Lugano 2014 Criteria
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End point description:

The plan was for the IRC to evaluate responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT-based objective response: either a complete (CR) or partial response (PR). A CR required a complete metabolic response with a score of 1, 2, or 3 on the PET 5-point scale (5PS) for 18-fluorodeoxyglucose (FDG) uptake (scores range from 1 [no uptake above background] to 5 [uptake markedly higher than liver and/or new lesions]), with or without a residual mass in lymph nodes and extralymphatic sites; and a PR required a partial metabolic response with a score of 4 or 5 on the 5PS with reduced 18-FDG uptake compared with baseline and residual mass(es) of any size. For bone marrow involvement, the CR criteria required no evidence of FDG-avid disease, and the PR criteria required residual uptake higher than in normal marrow but reduced compared with baseline. Subjects without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[18]	0 ^[19]	0 ^[20]	0 ^[21]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[18] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[19] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[20] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[21] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[22]	0 ^[23]	0 ^[24]	0 ^[25]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[22] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[23] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[24] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

[25] - Sponsor terminated the study due to modest benefit achieved; responses were not analyzed by the IRC.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Lugano 2014 Criteria

End point title	Percentage of Participants with Objective Response at the End of Induction, Determined by the Investigator on the Basis of PET-CT Scans Using Lugano 2014 Criteria
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End point description:

The investigator was to evaluate responses at the end of induction treatment using Lugano 2014 criteria for malignant lymphoma for a PET-CT-based objective response: either a complete (CR) or partial response (PR). A CR required a complete metabolic response with a score of 1, 2, or 3 on the PET 5-point scale (SPS) for 18-fluorodeoxyglucose (FDG) uptake (scores range from 1 [no uptake above background] to 5 [uptake markedly higher than liver and/or new lesions]), with or without a residual mass in lymph nodes and extralymphatic sites; and a PR required a partial metabolic response with a

score of 4 or 5 on the 5PS with reduced 18-FDG uptake compared with baseline and residual mass(es) of any size. For bone marrow involvement, the CR criteria required no evidence of FDG-avid disease, and the PR criteria required residual uptake higher than in normal marrow but reduced compared with baseline. Participants without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
End point timeframe:	
Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)	

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[26]	0 ^[27]	0 ^[28]	0 ^[29]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[26] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[27] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[28] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[29] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[30]	0 ^[31]	0 ^[32]	0 ^[33]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[30] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[31] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[32] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[33] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Objective Response at the End of Induction, Determined by an IRC on the Basis of CT Scans Alone Using Lugano 2014 Criteria

End point title	Percentage of Participants with Objective Response at the End of Induction, Determined by an IRC on the Basis of CT Scans
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End point description:

The plan was for the IRC to evaluate responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a CT-based objective response: either a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in the LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria required all of the following: a $\geq 50\%$ decrease in sum of the product of perpendicular diameters of up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/normal, regressed, but no increase; and spleen must have regressed by $>50\%$ in length. Participants without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[34]	0 ^[35]	0 ^[36]	0 ^[37]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[34] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[35] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[36] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[37] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[38]	0 ^[39]	0 ^[40]	0 ^[41]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[38] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[39] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[40] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[41] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

Statistical analyses

Secondary: Percentage of Participants with Objective Response at the End of Induction, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria

End point title	Percentage of Participants with Objective Response at the End of Induction, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria
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End point description:

The investigator was to evaluate responses at the end of induction treatment using the Lugano 2014 response criteria for malignant lymphoma for a CT-based objective response: either a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in the LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria required all of the following: a $\geq 50\%$ decrease in sum of the product of perpendicular diameters of up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/normal, regressed, but no increase; and spleen must have regressed by $>50\%$ in length. Participants without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
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End point timeframe:

Within 6 to 8 weeks after Day 1 of Cycle 6 (up to approximately 28 weeks; 1 cycle is 28 days)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[42]	0 ^[43]	0 ^[44]	0 ^[45]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[42] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[43] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[44] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[45] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[46]	0 ^[47]	0 ^[48]	0 ^[49]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[46] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[47] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[48] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

[49] - Sponsor terminated the study due to modest benefit achieved; objective responses were not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Best Response of Complete Response or Partial Response During the Study, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria

End point title	Percentage of Participants with Best Response of Complete Response or Partial Response During the Study, Determined by the Investigator on the Basis of CT Scans Alone Using Lugano 2014 Criteria
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End point description:

The investigator was to evaluate responses during the study using the Lugano 2014 response criteria for malignant lymphoma for a CT-based best response of a complete (CR) or partial response (PR). The CR criteria required a complete radiologic response with all of the following: target nodes/nodal masses must regress to less than or equal to 1.5 cm in the LDi; no extralymphatic sites of disease; no non-measured or new lesions; enlarged organs regressing to normal size; and bone marrow normal by morphology (if indeterminate, immunohistochemistry negative). The PR criteria required all of the following: a $\geq 50\%$ decrease in sum of the product of perpendicular diameters of up to 6 target measurable nodes and extranodal sites; no new lesions; non-measured lesion that is absent/normal, regressed, but no increase; and spleen must have regressed by $>50\%$ in length. Participants without a post-baseline tumor assessment were to be considered non-responders.

End point type	Secondary
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End point timeframe:

Baseline, Cycle 2, end of induction (up to 6 cycles; 1 cycle is 28 days), every 2 months (FL) until end of maintenance or at 4 months (DLBCL) of consolidation treatment, and then every 6 months during follow-up until disease progression (up to 3.5 years)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[50]	0 ^[51]	0 ^[52]	0 ^[53]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[50] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[51] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[52] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[53] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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	mg/m ²	1000 mg	1000 mg	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[54]	0 ^[55]	0 ^[56]	0 ^[57]
Units: Percentage of participants				
number (confidence interval 90%)	(to)	(to)	(to)	(to)

Notes:

[54] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[55] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[56] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

[57] - Sponsor terminated the study due to modest benefit achieved; best responses were not analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Idasanutlin Concentrations in DLBCL and FL Participants at Nominal Sampling Timepoints Grouped by Idasanutlin Dose and Combination Partner (Obinutuzumab or Rituximab)

End point title	Plasma Idasanutlin Concentrations in DLBCL and FL Participants at Nominal Sampling Timepoints Grouped by Idasanutlin Dose and Combination Partner (Obinutuzumab or Rituximab) ^[58]
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End point description:

The concentration of idasanutlin was determined using a validated assay. The duplication of the predose timepoint (0 hours) on Day 5 as an additional 24-hour timepoint on Day 5 was done in order to conduct pharmacokinetics analysis via non-compartmental analysis, and to derive idasanutlin exposure estimates up to the 24-hour post Day 5 dosing. The value '999999' in the results table indicates that the geometric mean and coefficient of variation were not available because 0 participants were analyzed at a given timepoint.

End point type	Secondary
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End point timeframe:

Predose (0 hours) and 6 hours postdose on Day 1 of Cycles 1, 2, and 4; Predose (0 hours) and 2, 4, 6, and 24 hours postdose on Day 5 of Cycles 1 and 2; Predose (0 hours) and 6 and 24 hours postdose on Cycle 4, Day 5 (1 cycle is 28 days)

Notes:

[58] - 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: Data from subjects in the DLBCL and FL arms who received idasanutlin and obinutuzumab at the same doses (i.e., 100 mg + 1000 mg and 150 mg + 1000 mg, respectively) were pooled together for this PK analysis and reported under combined subject analysis sets.

End point values	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	DLBCL/FL Combined: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2	3	4	3
Units: nanograms per millilitre (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1: 0 hours (n=2,3,4,3,6)	0 (± 0)	0 (± 0)	0 (± 0)	0 (± 0)
Cycle 1, Day 1: 6 hours (n=2,3,4,3,6)	5540 (± 21.5)	2130 (± 91.3)	2980 (± 49.9)	1540 (± 21.6)
Cycle 1, Day 5: 0 hours (n=2,3,4,3,5)	4120 (± 27.3)	1660 (± 77.9)	2920 (± 56.8)	1150 (± 19.9)
Cycle 1, Day 5: 2 hours (n=2,3,4,3,5)	7850 (± 23)	2970 (± 53.2)	4970 (± 45.7)	1230 (± 20.8)
Cycle 1, Day 5: 4 hours (n=2,3,3,3,5)	7930 (± 15.5)	2910 (± 73.2)	5910 (± 54.6)	1670 (± 17.5)
Cycle 1, Day 5: 6 hours (n=2,3,3,3,5)	7310 (± 13.6)	2820 (± 68.7)	5200 (± 49.8)	1730 (± 15.5)

Cycle 1, Day 5: 24 hours (n=2,3,4,3,5)	4120 (± 27.3)	1660 (± 77.9)	2920 (± 56.8)	1150 (± 19.9)
Cycle 2, Day 1: 0 hours (n=0,3,0,3,10)	999999 (± 999999)	0 (± 0)	999999 (± 999999)	0 (± 0)
Cycle 2, Day 1: 6 hours (n=0,3,0,3,10)	999999 (± 999999)	1260 (± 49.8)	999999 (± 999999)	1660 (± 33.1)
Cycle 2, Day 5: 0 hours (n=0,2,0,0,7)	999999 (± 999999)	2400 (± 67)	999999 (± 999999)	999999 (± 999999)
Cycle 2, Day 5: 2 hours (n=0,0,0,0,5)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 2, Day 5: 4 hours (n=0,0,0,0,5)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 2, Day 5: 6 hours (n=0,0,0,0,7)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 2, Day 5: 24 hours (n=0,0,0,0,7)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 4, Day 1: 0 hours (n=0,0,0,0,4)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 4, Day 1: 6 hours (n=0,0,0,0,4)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 4, Day 5: 0 hours (n=0,0,0,0,3)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 4, Day 5: 6 hours (n=0,0,0,0,3)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Cycle 4, Day 5: 24 hours (n=0,0,0,0,3)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

End point values	DLBCL/FL Combined: Idasanutlin 150 mg + Obinutuzumab 1000 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: nanograms per millilitre (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1: 0 hours (n=2,3,4,3,6)	0 (± 0)			
Cycle 1, Day 1: 6 hours (n=2,3,4,3,6)	2210 (± 42.4)			
Cycle 1, Day 5: 0 hours (n=2,3,4,3,5)	2150 (± 46.4)			
Cycle 1, Day 5: 2 hours (n=2,3,4,3,5)	3570 (± 68.4)			
Cycle 1, Day 5: 4 hours (n=2,3,3,3,5)	4360 (± 67.6)			
Cycle 1, Day 5: 6 hours (n=2,3,3,3,5)	4220 (± 94.8)			
Cycle 1, Day 5: 24 hours (n=2,3,4,3,5)	2150 (± 46.4)			
Cycle 2, Day 1: 0 hours (n=0,3,0,3,10)	0 (± 0)			
Cycle 2, Day 1: 6 hours (n=0,3,0,3,10)	2480 (± 51.5)			
Cycle 2, Day 5: 0 hours (n=0,2,0,0,7)	2380 (± 27.2)			
Cycle 2, Day 5: 2 hours (n=0,0,0,0,5)	4050 (± 54.9)			
Cycle 2, Day 5: 4 hours (n=0,0,0,0,5)	4200 (± 38.2)			
Cycle 2, Day 5: 6 hours (n=0,0,0,0,7)	4010 (± 31.6)			
Cycle 2, Day 5: 24 hours (n=0,0,0,0,7)	2380 (± 27.2)			
Cycle 4, Day 1: 0 hours (n=0,0,0,0,4)	0 (± 0)			
Cycle 4, Day 1: 6 hours (n=0,0,0,0,4)	2730 (± 9.9)			
Cycle 4, Day 5: 0 hours (n=0,0,0,0,3)	2600 (± 25.6)			
Cycle 4, Day 5: 6 hours (n=0,0,0,0,3)	5210 (± 19.5)			

Cycle 4, Day 5: 24 hours (n=0,0,0,0,3)	2600 (\pm 25.6)			
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Statistical analyses

No statistical analyses for this end point

Secondary: Serum Obinutuzumab Concentrations in DLBCL and FL Participants at Nominal Sampling Timepoints

End point title	Serum Obinutuzumab Concentrations in DLBCL and FL Participants at Nominal Sampling Timepoints
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End point description:

End point type	Secondary
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End point timeframe:

Pre-infusion (0 hour) and 0.5 hours after end of obinutuzumab infusion on Day 1 of Cycles 1, 2, 4, and 6

End point values	DLBCL/FL: Idasanutlin 100/150/200 mg + Obinutuzumab 1000 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: micrograms per millilitre (μ g/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1: 0 hours (n=16)	0 (\pm 0)			
Cycle 1, Day 1: 0.5 hours (n=13)	397 (\pm 32.9)			
Cycle 2, Day 1: 0 hours (n=12)	325 (\pm 59.8)			
Cycle 2, Day 1: 0.5 hours (n=12)	703 (\pm 40.2)			
Cycle 4, Day 1: 0 hours (n=7)	346 (\pm 46.1)			
Cycle 4, Day 1: 0.5 hours (n=7)	685 (\pm 38.5)			
Cycle 6, Day 1: 0 hours (n=7)	303 (\pm 49.5)			
Cycle 6, Day 1: 0.5 hours (n=7)	639 (\pm 34.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Rituximab Concentrations in DLBCL Participants at Nominal Sampling Timepoints

End point title	Serum Rituximab Concentrations in DLBCL Participants at Nominal Sampling Timepoints
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End point description:

End point type	Secondary
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End point timeframe:

Pre-infusion (0 hours) at Cycle 1, Day 1 and Cycle 2, Day 1; Post-infusion 0.5 hours at Cycle 1, Day 1 (1 cycle is 28 days)

End point values	DLBCL Combined: Idasanutlin 150/200 mg + Rituximab 375 mg/m ²			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: micrograms per millilitre (µg/mL)				
geometric mean (geometric coefficient of variation)				
Cycle 1, Day 1: 0 hours (n=7)	0 (± 0)			
Cycle 1, Day 1: 0.5 hours (n=6)	197 (± 14.1)			
Cycle 2, Day 1: 0 hours (n=3)	37.9 (± 58.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Safety Summary of the Number of Participants with at Least One Adverse Event by Type and Severity According to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0 (NCI CTCAE v4.0)

End point title	Safety Summary of the Number of Participants with at Least One Adverse Event by Type and Severity According to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0 (NCI CTCAE v4.0)
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End point description:

The adverse event (AE) severity grading scale for the NCI CTCAE v4.0 was used for assessing AE severity. Any AEs that were not specifically listed in the NCI CTCAE, v4.0 were graded per the following 5 grades: Grade 1 = mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; or intervention not indicated. Grade 2 = moderate; minimal, local, or non-invasive intervention indicated; or limiting age-appropriate instrumental activities of daily living. Grade 3 = severe or medically significant, but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; or limiting self-care activities of daily living. Grade 4 = life-threatening consequences or urgent intervention indicated. Grade 5 = death related to AE. The terms "severe" and "serious" are not synonymous and are independently assessed for each AE. Multiple occurrences of AEs were counted only once per participant at the highest (worst) grade.

End point type	Secondary
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End point timeframe:

From first dose until 90 days after the last dose of study drug treatment (up to 31 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: Participants				
Any Adverse Event (AE)	1	3	2	3
Grade 5 AE	0	0	0	0
Grade 3-5 AE	1	3	2	2
Serious AE	1	1	1	0
AE Leading to any Study Treatment Discontinuation	0	1	2	1
AE Leading to Dose Reductions	0	0	0	0
AE Leading to Dose Interruptions	1	0	0	0
AE Leading to Study Discontinuation	0	0	0	0
Related to Idasanutlin - Any AE	1	2	2	2
Related to Idasanutlin - Grade 3-5 AE	1	2	2	1
Related to Idasanutlin - Serious AE	1	0	1	0
Related to Obinutuzumab - Any AE	1	2	2	0
Related to Obinutuzumab - Grade 3-5 AE	1	1	2	0
Related to Obinutuzumab - Serious AE	0	0	1	0
Related to Rituximab - Any AE	0	0	0	2
Related to Rituximab - Grade 3-5 AE	0	0	0	1
Related to Rituximab - Serious AE	0	0	0	0
Related AE Leading to Treatment Discontinuation	0	0	2	1

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Participants				
Any Adverse Event (AE)	4	2	4	5
Grade 5 AE	0	0	0	0
Grade 3-5 AE	3	1	3	4
Serious AE	2	1	1	2
AE Leading to any Study Treatment Discontinuation	1	0	2	2
AE Leading to Dose Reductions	0	0	0	0
AE Leading to Dose Interruptions	1	0	3	1
AE Leading to Study Discontinuation	0	0	0	0
Related to Idasanutlin - Any AE	4	1	4	5
Related to Idasanutlin - Grade 3-5 AE	2	1	3	4
Related to Idasanutlin - Serious AE	1	0	0	2
Related to Obinutuzumab - Any AE	1	0	3	5

Related to Obinutuzumab - Grade 3-5 AE	0	0	2	3
Related to Obinutuzumab - Serious AE	0	0	1	1
Related to Rituximab - Any AE	2	0	0	0
Related to Rituximab - Grade 3-5 AE	0	0	0	0
Related to Rituximab - Serious AE	0	0	0	0
Related AE Leading to Treatment Discontinuation	1	0	2	1

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline Value and Change from Baseline Values of Systolic Blood Pressure at Specified Timepoints

End point title	Baseline Value and Change from Baseline Values of Systolic Blood Pressure at Specified Timepoints
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End point description:

Vital signs were measured prior to the infusion while the participant was in a seated position. The change from baseline value was calculated by subtracting the post-baseline value from the baseline value. The value '999999' in the results table indicates that the mean and standard deviation are not available because 0 participants were analyzed at a given timepoint. The value '9999999' in the results table indicates that the standard deviation could not be calculated using data from a single participant. Maint. = maintenance

End point type	Secondary
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End point timeframe:

Baseline, Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 (up to 6 cycles; 1 cycle is 28 days), and then every 2 months (FL) or every month (DLBCL) until end of maintenance or consolidation treatment, respectively (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
Baseline (BL) Value at Visit (n=1,3,2,3,4,2,4,5)	176.0 (± 9999999)	124.0 (± 7.9)	107.5 (± 2.1)	125.7 (± 39.4)
Change from BL: Cycle 1 Day 1 (n=1,3,2,3,4,2,4,5)	-34.0 (± 9999999)	-2.0 (± 10.5)	-5.0 (± 4.2)	-2.7 (± 14.6)
Change from BL: Cycle 1 Day 8 (n=1,3,2,0,0,2,4,5)	-4.0 (± 9999999)	-5.0 (± 8.5)	-7.0 (± 8.5)	999999 (± 999999)
Change from BL: Cycle 1 Day 15 (n=1,3,0,0,0,2,3,5)	24.0 (± 9999999)	-5.3 (± 14.6)	999999 (± 999999)	999999 (± 999999)
Change from BL: Cycle 2 Day 1 (n=1,2,0,2,0,1,2,5)	-17.0 (± 9999999)	-3.5 (± 19.1)	999999 (± 999999)	0.0 (± 39.6)
Change from BL: Cycle 3 Day 1 (n=1,1,0,0,0,2,2,3)	-1.0 (± 9999999)	11.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)

Change from BL: Cycle 4 Day 1 (n=1,0,0,0,0,2,2,1)	-22.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Cycle 5 Day 1 (n=1,0,0,0,0,2,2,2)	-21.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Cycle 6 Day 1 (n=0,0,0,0,0,1,1,2)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 1 (n=0,0,0,0,0,1,0,2)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 3 (n=0,0,0,0,0,1,0,2)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 5 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 7 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 9 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 11 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 13 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 15 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 17 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 19 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 21 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Follow-Up (n=1,0,2,2,2,2,4,4)	-32.0 (± 9999999)	999999 (± 999999)	-3.5 (± 9.2)	-25.0 (± 55.2)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
Baseline (BL) Value at Visit (n=1,3,2,3,4,2,4,5)	119.0 (± 16.8)	120.5 (± 17.7)	109.3 (± 9.1)	116.4 (± 10.5)
Change from BL: Cycle 1 Day 1 (n=1,3,2,3,4,2,4,5)	-0.8 (± 10.6)	-3.5 (± 10.6)	3.5 (± 9.4)	4.8 (± 14.8)
Change from BL: Cycle 1 Day 8 (n=1,3,2,0,0,2,4,5)	999999 (± 999999)	-6.5 (± 6.4)	-2.3 (± 15.2)	6.4 (± 10.3)
Change from BL: Cycle 1 Day 15 (n=1,3,0,0,0,2,3,5)	999999 (± 999999)	-3.5 (± 7.8)	9.7 (± 13.4)	8.0 (± 12.9)
Change from BL: Cycle 2 Day 1 (n=1,2,0,2,0,1,2,5)	999999 (± 999999)	-14.0 (± 9999999)	4.5 (± 4.9)	8.6 (± 10.4)
Change from BL: Cycle 3 Day 1 (n=1,1,0,0,0,2,2,3)	999999 (± 999999)	-13.5 (± 3.5)	10.5 (± 2.1)	7.0 (± 8.9)
Change from BL: Cycle 4 Day 1 (n=1,0,0,0,0,2,2,1)	999999 (± 999999)	12.5 (± 27.6)	2.0 (± 1.4)	-10.0 (± 9999999)
Change from BL: Cycle 5 Day 1 (n=1,0,0,0,0,2,2,2)	999999 (± 999999)	0.5 (± 4.9)	12.5 (± 9.2)	8.5 (± 9.2)

Change from BL: Cycle 6 Day 1 (n=0,0,0,0,0,1,1,2)	999999 (± 999999)	-2.0 (± 9999999)	20.0 (± 9999999)	0.5 (± 0.7)
Change from BL: Maint. Month 1 (n=0,0,0,0,0,1,0,2)	999999 (± 999999)	-14.0 (± 9999999)	999999 (± 999999)	14.0 (± 9.9)
Change from BL: Maint. Month 3 (n=0,0,0,0,0,1,0,2)	999999 (± 999999)	9.0 (± 9999999)	999999 (± 999999)	7.5 (± 10.6)
Change from BL: Maint. Month 5 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	-12.0 (± 9999999)	999999 (± 999999)	9.0 (± 9999999)
Change from BL: Maint. Month 7 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	-5.0 (± 9999999)	999999 (± 999999)	0.0 (± 9999999)
Change from BL: Maint. Month 9 (n=0,0,0,0,0,1,0,1)	999999 (± 999999)	-3.0 (± 9999999)	999999 (± 999999)	7.0 (± 9999999)
Change from BL: Maint. Month 11 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	-5.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 13 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	-5.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 15 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	-9.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 17 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	-35.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 19 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	2.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Maint. Month 21 (n=0,0,0,0,0,1,0,0)	999999 (± 999999)	-21.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL: Follow-Up (n=1,0,2,2,2,2,4,4)	-3.5 (± 0.7)	9.5 (± 3.5)	20.0 (± 15.5)	-1.3 (± 9.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline Value and Change from Baseline Values of Diastolic Blood Pressure at Specified Timepoints

End point title	Baseline Value and Change from Baseline Values of Diastolic Blood Pressure at Specified Timepoints
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End point description:

Vital signs were measured prior to the infusion while the participant was in a seated position. The change from baseline value was calculated by subtracting the post-baseline value from the baseline value. The value '999999' in the results table indicates that the mean and standard deviation are not available because 0 participants were analyzed at a given timepoint. The value '9999999' in the results table indicates that the standard deviation could not be calculated using data from a single participant. Maint. = maintenance

End point type	Secondary
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End point timeframe:

Baseline, Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 (up to 6 cycles; 1 cycle is 28 days), and then every 2 months (FL) or every month (DLBCL) until end of maintenance or consolidation treatment, respectively (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
Baseline (BL) Value at Visit	100.0 (± 9999999)	67.3 (± 12.1)	72.0 (± 9.9)	72.3 (± 12.3)
Change from BL at Cycle 1 Day 1	-17.0 (± 9999999)	-2.0 (± 19.5)	-2.5 (± 2.1)	7.3 (± 23.1)
Change from BL at Cycle 1 Day 8	-1.0 (± 9999999)	1.3 (± 15.0)	-2.5 (± 6.4)	999999 (± 999999)
Change from BL at Cycle 1 Day 15	-1.0 (± 9999999)	3.0 (± 16.4)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 2 Day 1	7.0 (± 9999999)	0.0 (± 17.0)	999999 (± 999999)	3.5 (± 13.4)
Change from BL at Cycle 3 Day 1	3.0 (± 9999999)	3.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 4 Day 1	-4.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 5 Day 1	-2.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 3	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 5	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 7	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 9	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 11	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	-16.0 (± 9999999)	999999 (± 999999)	-9.0 (± 21.2)	-15.5 (± 20.5)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: millimeters of mercury (mmHg)				
arithmetic mean (standard deviation)				
Baseline (BL) Value at Visit	70.3 (± 7.6)	71.5 (± 9.2)	76.3 (± 12.7)	65.8 (± 6.9)
Change from BL at Cycle 1 Day 1	-2.3 (± 7.4)	-2.0 (± 4.2)	3.0 (± 4.9)	6.4 (± 2.1)
Change from BL at Cycle 1 Day 8	999999 (± 999999)	-2.0 (± 0.0)	-6.5 (± 1.3)	9.2 (± 8.5)
Change from BL at Cycle 1 Day 15	999999 (± 999999)	6.0 (± 4.2)	0.0 (± 6.6)	2.4 (± 8.3)
Change from BL at Cycle 2 Day 1	999999 (± 999999)	0.0 (± 9999999)	-8.0 (± 2.8)	12.0 (± 5.1)
Change from BL at Cycle 3 Day 1	999999 (± 999999)	-5.5 (± 6.4)	-1.0 (± 4.2)	5.3 (± 5.0)
Change from BL at Cycle 4 Day 1	999999 (± 999999)	3.0 (± 8.5)	-8.0 (± 7.1)	7.0 (± 9999999)
Change from BL at Cycle 5 Day 1	999999 (± 999999)	3.5 (± 0.7)	-2.0 (± 7.1)	2.5 (± 4.9)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	10.0 (± 9999999)	9.0 (± 9999999)	2.5 (± 3.5)
Change from BL at Maint. Month 1	999999 (± 999999)	0.0 (± 9999999)	999999 (± 9999999)	2.0 (± 0.0)
Change from BL at Maint. Month 3	999999 (± 999999)	14.0 (± 9999999)	999999 (± 9999999)	5.0 (± 8.5)
Change from BL at Maint. Month 5	999999 (± 999999)	-7.0 (± 9999999)	999999 (± 9999999)	-5.0 (± 9999999)
Change from BL at Maint. Month 7	999999 (± 999999)	7.0 (± 9999999)	999999 (± 9999999)	-1.0 (± 9999999)
Change from BL at Maint. Month 9	999999 (± 999999)	6.0 (± 9999999)	999999 (± 9999999)	3.0 (± 9999999)
Change from BL at Maint. Month 11	999999 (± 999999)	-13.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Maint. Month 13	999999 (± 999999)	1.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Maint. Month 15	999999 (± 999999)	9.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Maint. Month 17	999999 (± 999999)	-4.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Maint. Month 19	999999 (± 999999)	7.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Maint. Month 21	999999 (± 999999)	0.0 (± 9999999)	999999 (± 9999999)	999999 (± 9999999)
Change from BL at Follow-Up	4.0 (± 4.2)	10.5 (± 2.1)	7.5 (± 20.2)	9.3 (± 3.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline Value and Change from Baseline Values of Pulse Rate at Specified Timepoints

End point title	Baseline Value and Change from Baseline Values of Pulse Rate at Specified Timepoints
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End point description:

Vital signs were measured prior to the infusion while the participant was in a seated position. The change from baseline value was calculated by subtracting the post-baseline value from the baseline value. The value '999999' in the results table indicates that the mean and standard deviation are not

available because 0 participants were analyzed at a given timepoint. The value '9999999' in the results table indicates that the standard deviation could not be calculated using data from a single participant. Maint. = maintenance

End point type	Secondary
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End point timeframe:

Baseline, Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 (up to 6 cycles; 1 cycle is 28 days), and then every 2 months (FL) or every month (DLBCL) until end of maintenance or consolidation treatment, respectively (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: beats per minute				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	73.0 (± 9999999)	65.7 (± 1.2)	100.5 (± 17.7)	81.7 (± 3.1)
Change from BL at Cycle 1 Day 1	10.0 (± 9999999)	15.7 (± 21.5)	-9.0 (± 8.5)	0.0 (± 9.8)
Change from BL at Cycle 1 Day 8	-2.0 (± 9999999)	11.0 (± 2.0)	-2.0 (± 1.4)	999999 (± 999999)
Change from BL at Cycle 1 Day 15	-11.0 (± 9999999)	12.7 (± 13.4)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 2 Day 1	4.0 (± 9999999)	17.5 (± 17.7)	999999 (± 999999)	7.0 (± 1.4)
Change from BL at Cycle 3 Day 1	-1.0 (± 9999999)	19.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 4 Day 1	1.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 5 Day 1	15.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 3	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 5	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 7	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 9	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 11	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

Change from BL at Maint. Month 21	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	15.0 (± 9999999)	999999 (± 999999)	-20.0 (± 18.4)	11.5 (± 10.6)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: beats per minute				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	76.0 (± 10.6)	77.5 (± 12.0)	79.5 (± 18.6)	80.2 (± 9.9)
Change from BL at Cycle 1 Day 1	8.8 (± 12.0)	2.5 (± 14.8)	2.3 (± 6.4)	9.0 (± 11.1)
Change from BL at Cycle 1 Day 8	999999 (± 999999)	-0.5 (± 20.5)	2.3 (± 6.4)	9.0 (± 11.1)
Change from BL at Cycle 1 Day 15	999999 (± 999999)	-3.5 (± 16.3)	-1.7 (± 13.1)	3.2 (± 14.5)
Change from BL at Cycle 2 Day 1	999999 (± 999999)	-17.0 (± 999999)	-2.5 (± 4.9)	6.4 (± 9.7)
Change from BL at Cycle 3 Day 1	999999 (± 999999)	-1.5 (± 16.3)	-4.5 (± 20.5)	-3.5 (± 10.6)
Change from BL at Cycle 4 Day 1	999999 (± 999999)	-7.0 (± 12.7)	-5.0 (± 5.7)	4.0 (± 999999)
Change from BL at Cycle 5 Day 1	999999 (± 999999)	-6.5 (± 10.6)	3.0 (± 28.3)	6.5 (± 4.9)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	-1.0 (± 999999)	31.0 (± 999999)	15.0 (± 2.8)
Change from BL at Maint. Month 1	999999 (± 999999)	6.0 (± 999999)	999999 (± 999999)	10.0 (± 5.7)
Change from BL at Maint. Month 3	999999 (± 999999)	0.0 (± 999999)	999999 (± 999999)	2.0 (± 9.9)
Change from BL at Maint. Month 5	999999 (± 999999)	-5.0 (± 999999)	999999 (± 999999)	11.0 (± 999999)
Change from BL at Maint. Month 7	999999 (± 999999)	1.0 (± 999999)	999999 (± 999999)	2.0 (± 999999)
Change from BL at Maint. Month 9	999999 (± 999999)	6.0 (± 999999)	999999 (± 999999)	11.0 (± 999999)
Change from BL at Maint. Month 11	999999 (± 999999)	18.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	11.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	2.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	-2.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	1.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	13.0 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	23.5 (± 20.5)	15.0 (± 8.5)	5.8 (± 14.8)	10.3 (± 9.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline Value and Change from Baseline Values of Respiratory Rate at Specified Timepoints

End point title	Baseline Value and Change from Baseline Values of Respiratory Rate at Specified Timepoints
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End point description:

Vital signs were measured prior to the infusion while the participant was in a seated position. The change from baseline value was calculated by subtracting the post-baseline value from the baseline value. The value '999999' in the results table indicates that the mean and standard deviation are not available because 0 participants were analyzed at a given timepoint. The value '9999999' in the results table indicates that the standard deviation could not be calculated using data from a single participant. Maint. = maintenance

End point type	Secondary
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End point timeframe:

Baseline, Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 (up to 6 cycles; 1 cycle is 28 days), and then every 2 months (FL) or every month (DLBCL) until end of maintenance or consolidation treatment, respectively (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: breaths per minute				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	18.0 (± 9999999)	17.0 (± 2.6)	19.0 (± 1.4)	17.0 (± 1.7)
Change from BL at Cycle 1 Day 1	0.0 (± 9999999)	0.7 (± 1.2)	-1.0 (± 1.4)	-0.7 (± 1.2)
Change from BL at Cycle 1 Day 8	0.0 (± 9999999)	-1.7 (± 2.1)	-1.0 (± 1.4)	999999 (± 999999)
Change from BL at Cycle 1 Day 15	0.0 (± 9999999)	-3.5 (± 2.1)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 2 Day 1	0.0 (± 9999999)	-2.5 (± 3.5)	999999 (± 999999)	0.5 (± 0.7)
Change from BL at Cycle 3 Day 1	2.0 (± 9999999)	-4.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 4 Day 1	-2.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 5 Day 1	0.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 3	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 5	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 7	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)

Change from BL at Maint. Month 9	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 11	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	-2.0 (± 9999999)	999999 (± 999999)	-2.0 (± 2.8)	-4.0 (± 9999999)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non- Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non- Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: breaths per minute				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	17.0 (± 2.0)	16.0 (± 0.0)	16.0 (± 3.3)	16.8 (± 3.0)
Change from BL at Cycle 1 Day 1	0.3 (± 1.3)	1.0 (± 1.4)	2.3 (± 0.5)	0.0 (± 0.0)
Change from BL at Cycle 1 Day 8	999999 (± 999999)	0.0 (± 0.0)	2.0 (± 4.0)	0.0 (± 2.4)
Change from BL at Cycle 1 Day 15	999999 (± 999999)	1.0 (± 1.4)	1.7 (± 1.5)	-0.2 (± 2.7)
Change from BL at Cycle 2 Day 1	999999 (± 999999)	0.0 (± 9999999)	4.0 (± 5.7)	0.0 (± 4.6)
Change from BL at Cycle 3 Day 1	999999 (± 999999)	0.0 (± 0.0)	4.0 (± 5.7)	-1.0 (± 4.2)
Change from BL at Cycle 4 Day 1	999999 (± 999999)	0.0 (± 0.0)	2.0 (± 2.8)	4.0 (± 9999999)
Change from BL at Cycle 5 Day 1	999999 (± 999999)	0.0 (± 0.0)	1.0 (± 1.4)	0.0 (± 5.7)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	-4.0 (± 9999999)	5.0 (± 9999999)	-2.0 (± 2.8)
Change from BL at Maint. Month 1	999999 (± 999999)	-4.0 (± 9999999)	999999 (± 999999)	-1.0 (± 4.2)
Change from BL at Maint. Month 3	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	-2.0 (± 2.8)
Change from BL at Maint. Month 5	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	-4.0 (± 9999999)
Change from BL at Maint. Month 7	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	-4.0 (± 9999999)
Change from BL at Maint. Month 9	999999 (± 999999)	2.0 (± 9999999)	999999 (± 999999)	-4.0 (± 9999999)
Change from BL at Maint. Month 11	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)

Change from BL at Maint. Month 15	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	2.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	0.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	2.0 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	0.0 (± 2.8)	1.0 (± 1.4)	3.3 (± 3.2)	-0.7 (± 3.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Baseline Value and Change from Baseline Values of Body Temperature at Specified Timepoints

End point title	Baseline Value and Change from Baseline Values of Body Temperature at Specified Timepoints
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End point description:

Vital signs were measured prior to the infusion while the participant was in a seated position. The change from baseline value was calculated by subtracting the post-baseline value from the baseline value. The value '999999' in the results table indicates that the mean and standard deviation are not available because 0 participants were analyzed at a given timepoint. The value '9999999' in the results table indicates that the standard deviation could not be calculated using data from a single participant. Maint. = maintenance

End point type	Secondary
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End point timeframe:

Baseline, Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 (up to 6 cycles; 1 cycle is 28 days), and then every 2 months (FL) or every month (DLBCL) until end of maintenance or consolidation treatment, respectively (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: degrees Celsius (C)				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	36.60 (± 9999999)	36.47 (± 0.45)	36.35 (± 0.21)	36.83 (± 0.15)
Change from BL at Cycle 1 Day 1	0.00 (± 9999999)	0.00 (± 0.92)	-0.15 (± 0.21)	-0.07 (± 0.15)
Change from BL at Cycle 1 Day 8	0.10 (± 9999999)	0.37 (± 0.50)	0.95 (± 0.85)	999999 (± 999999)
Change from BL at Cycle 1 Day 15	0.10 (± 9999999)	0.20 (± 0.82)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 2 Day 1	0.00 (± 9999999)	0.10 (± 0.14)	999999 (± 999999)	-0.30 (± 0.14)
Change from BL at Cycle 3 Day 1	-0.20 (± 9999999)	-0.10 (± 9999999)	999999 (± 999999)	999999 (± 999999)

Change from BL at Cycle 4 Day 1	0.00 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 5 Day 1	0.20 (± 9999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 1	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 3	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 5	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 7	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 9	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 11	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	0.10 (± 9999999)	999999 (± 999999)	0.00 (± 0.14)	-0.40 (± 0.14)

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: degrees Celsius (C)				
arithmetic mean (standard deviation)				
Baseline (BL) - Value at Visit	36.58 (± 0.34)	36.55 (± 0.21)	36.50 (± 0.18)	36.70 (± 3.3)
Change from BL at Cycle 1 Day 1	0.18 (± 0.33)	0.05 (± 0.49)	0.30 (± 0.22)	-0.18 (± 0.30)
Change from BL at Cycle 1 Day 8	999999 (± 999999)	0.30 (± 0.28)	-0.13 (± 0.22)	0.10 (± 0.45)
Change from BL at Cycle 1 Day 15	999999 (± 999999)	0.20 (± 0.28)	-0.23 (± 0.45)	-0.18 (± 0.26)
Change from BL at Cycle 2 Day 1	999999 (± 999999)	-0.50 (± 9999999)	-0.25 (± 0.49)	-0.04 (± 0.09)
Change from BL at Cycle 3 Day 1	999999 (± 999999)	-0.10 (± 0.42)	-0.50 (± 0.28)	-0.17 (± 0.21)
Change from BL at Cycle 4 Day 1	999999 (± 999999)	0.05 (± 0.64)	0.05 (± 0.21)	-0.10 (± 9999999)
Change from BL at Cycle 5 Day 1	999999 (± 999999)	0.35 (± 0.64)	-0.35 (± 0.49)	-0.20 (± 0.14)
Change from BL at Cycle 6 Day 1	999999 (± 999999)	0.20 (± 9999999)	0.20 (± 9999999)	-0.05 (± 0.21)

Change from BL at Maint. Month 1	999999 (± 999999)	0.60 (± 9999999)	999999 (± 999999)	-0.20 (± 0.14)
Change from BL at Maint. Month 3	999999 (± 999999)	0.40 (± 9999999)	999999 (± 999999)	-0.20 (± 0.57)
Change from BL at Maint. Month 5	999999 (± 999999)	0.20 (± 9999999)	999999 (± 999999)	-0.20 (± 9999999)
Change from BL at Maint. Month 7	999999 (± 999999)	0.60 (± 9999999)	999999 (± 999999)	-0.10 (± 9999999)
Change from BL at Maint. Month 9	999999 (± 999999)	0.30 (± 9999999)	999999 (± 999999)	0.20 (± 9999999)
Change from BL at Maint. Month 11	999999 (± 999999)	0.70 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 13	999999 (± 999999)	0.40 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 15	999999 (± 999999)	0.70 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 17	999999 (± 999999)	0.40 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 19	999999 (± 999999)	0.80 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Maint. Month 21	999999 (± 999999)	0.50 (± 9999999)	999999 (± 999999)	999999 (± 999999)
Change from BL at Follow-Up	0.53 (± 0.71)	0.30 (± 0.57)	-0.15 (± 0.47)	-0.10 (± 0.24)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants by Electrocardiogram (ECG) Results Assessment Shift from Baseline to Specified Post-Baseline Timepoints

End point title	Number of Participants by Electrocardiogram (ECG) Results Assessment Shift from Baseline to Specified Post-Baseline Timepoints
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End point description:

Single, resting, 12-lead ECG recordings were to be obtained after the participant had been resting in a supine position for at least 10 minutes. Any morphologic waveform changes or other ECG abnormalities were to be documented and clinical significance was determined based on the presence of symptoms, per the investigator's judgment. If the ECG assessment was missing at baseline then it was recorded as "Missing". The ECG results assessments are presented as the shift from baseline to post-baseline assessments at each timepoint. The value '999999' indicates that data is not available because 0 participants were analyzed. Abnorm, CS = Abnormal, Clinically Significant; Abnorm, not CS = Abnormal, not Clinically Significant; BL = baseline; C1D1 = Induction Cycle 1 Day 1; C4D1 = Induction Cycle 4 Day 1; EOI = End of Induction Treatment - Completion/Discontinuation; EOM = End of Maintenance Treatment - Completion/Discontinuation; M1 = Maintenance Month 1; U = Unscheduled Visit

End point type	Secondary
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End point timeframe:

Baseline, Induction Cycle 1 Day 1 and Cycle 4 Day 1, End of Induction (up to 6 cycles; 1 cycle is 28 days); Every 2 months during maintenance treatment from Months 1-23; End of Maintenance (up to 24 months); Unscheduled Visits (as clinically indicated)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: Participants				
C1D1: Norm at BL & Visit (n=0,3,2,3,4,1,4,5)	999999	1	1	0
C1D1:Norm(BL) to Abnorm,not CS (n=0,3,2,3,4,1,4,5)	999999	1	0	1
C1D1:Abnorm,not CS(BL) to Norm (n=0,3,2,3,4,1,4,5)	999999	0	0	1
C1D1:Abnorm,not CS at BL&Visit (n=0,3,2,3,4,1,4,5)	999999	1	1	1
C4D1: Norm at BL & Visit (n=1,0,0,0,0,2,2,2)	0	999999	999999	999999
C4D1:Norm(BL) to Abnorm, not CS(n=1,0,0,0,0,2,2,2)	1	999999	999999	999999
C4D1:Abnorm, not CS(BL) to Norm(n=1,0,0,0,0,2,2,2)	0	999999	999999	999999
C4D1:Abnorm,not CS at BL&Visit (n=1,0,0,0,0,2,2,2)	0	999999	999999	999999
C4D1:Missing (BL) to Norm (n=1,0,0,0,0,2,2,2)	0	999999	999999	999999
EOI: Norm at BL & Visit (n=1,2,2,1,3,2,3,3)	0	0	1	0
EOI:Norm(BL) to Abnorm,not CS (n=1,2,2,1,3,2,3,3)	1	1	0	0
EOI:Abnorm,not CS at BL&Visit (n=1,2,2,1,3,2,3,3)	0	1	1	1
EOI: Missing (BL) to Norm (n=1,2,2,1,3,2,3,3)	0	0	0	0
M1: Norm at BL & Visit (n=0,0,0,0,0,0,0,2)	999999	999999	999999	999999
M1: Abnorm,not CS at BL&Visit (n=0,0,0,0,0,0,0,2)	999999	999999	999999	999999
M3: Abnorm, not CS(BL) to Norm (n=0,0,0,0,0,0,0,1)	999999	999999	999999	999999
M5: Abnorm, not CS(BL) to Norm (n=0,0,0,0,0,0,0,1)	999999	999999	999999	999999
M7:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M9:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M11:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M13:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M15:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M17:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M19:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M21:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999
M23:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	999999	999999	999999

EOM: Norm at BL & Visit (n=0,0,0,0,0,1,1,0)	999999	999999	999999	999999
EOM:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,1,0)	999999	999999	999999	999999
U: Norm at BL & Visit (n=1,0,0,0,0,1,2,2)	1	999999	999999	999999
U:Norm (BL) to Abnorm, not CS (n=1,0,0,0,0,1,2,2)	0	999999	999999	999999
U:Abnorm, not CS(BL) to Norm (n=1,0,0,0,0,1,2,2)	0	999999	999999	999999
U:Abnorm,not CS at BL&Visit (n=1,0,0,0,0,1,2,2)	0	999999	999999	999999
U:Abnorm,notCS(BL) to Abnorm,CS(n=1,0,0,0,0,1,2,2)	0	999999	999999	999999

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non- Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non- Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Participants				
C1D1: Norm at BL & Visit (n=0,3,2,3,4,1,4,5)	2	0	4	2
C1D1:Norm(BL) to Abnorm,not CS (n=0,3,2,3,4,1,4,5)	0	0	0	0
C1D1:Abnorm,not CS(BL) to Norm (n=0,3,2,3,4,1,4,5)	0	0	0	1
C1D1:Abnorm,not CS at BL&Visit (n=0,3,2,3,4,1,4,5)	2	1	0	2
C4D1: Norm at BL & Visit (n=1,0,0,0,0,2,2,2)	999999	0	2	1
C4D1:Norm(BL) to Abnorm, not CS(n=1,0,0,0,0,2,2,2)	999999	0	0	0
C4D1:Abnorm, not CS(BL) to Norm(n=1,0,0,0,0,2,2,2)	999999	0	0	1
C4D1:Abnorm,not CS at BL&Visit (n=1,0,0,0,0,2,2,2)	999999	1	0	0
C4D1:Missing (BL) to Norm (n=1,0,0,0,0,2,2,2)	999999	1	0	0
EOI: Norm at BL & Visit (n=1,2,2,1,3,2,3,3)	2	0	3	2
EOI:Norm(BL) to Abnorm,not CS (n=1,2,2,1,3,2,3,3)	0	0	0	0
EOI:Abnorm,not CS at BL&Visit (n=1,2,2,1,3,2,3,3)	1	1	0	1
EOI: Missing (BL) to Norm (n=1,2,2,1,3,2,3,3)	0	1	0	0
M1: Norm at BL & Visit (n=0,0,0,0,0,0,0,2)	999999	999999	999999	1
M1: Abnorm,not CS at BL&Visit (n=0,0,0,0,0,0,0,2)	999999	999999	999999	1
M3: Abnorm, not CS(BL) to Norm (n=0,0,0,0,0,0,0,1)	999999	999999	999999	1
M5: Abnorm, not CS(BL) to Norm (n=0,0,0,0,0,0,0,1)	999999	999999	999999	1

M7:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M9:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M11:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M13:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M15:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M17:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M19:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M21:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
M23:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,0,0)	999999	1	999999	999999
EOM: Norm at BL & Visit (n=0,0,0,0,0,1,1,0)	999999	0	1	999999
EOM:Missing(BL) to Abnorm,notCS(n=0,0,0,0,0,1,1,0)	999999	1	0	999999
U: Norm at BL & Visit (n=1,0,0,0,0,1,2,2)	999999	0	1	0
U:Norm (BL) to Abnorm, not CS (n=1,0,0,0,0,1,2,2)	999999	0	1	0
U:Abnorm, not CS(BL) to Norm (n=1,0,0,0,0,1,2,2)	999999	0	0	1
U:Abnorm,not CS at BL&Visit (n=1,0,0,0,0,1,2,2)	999999	1	0	0
U:Abnorm,notCS(BL) to Abnorm,CS(n=1,0,0,0,0,1,2,2)	999999	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Hematology Laboratory Test Results Shift Table: Number of Participants by Highest NCI-CTCAE v4.0 Grade at Baseline to Highest Grade Post-Baseline

End point title	Hematology Laboratory Test Results Shift Table: Number of Participants by Highest NCI-CTCAE v4.0 Grade at Baseline to Highest Grade Post-Baseline
End point description:	Clinical laboratory tests for hematology parameters were performed at local laboratories and abnormalities (High or Low) were based on local reference ranges. Severity was determined according to NCI-CTCAE v4.0, from Grades 1 (least severe) to 4 (most severe). Grade 0 indicates that the results were within the normal range. Not every abnormal laboratory value qualified as an adverse event, only if it met any of the following criteria: clinically significant (per investigator); accompanied by clinical symptoms; resulted in a change in study treatment; or required a medical intervention or a change in concomitant therapy. For multiple post-baseline abnormalities on any given parameter, only the participant's highest grade was reported. Abs. = absolute count; BL = baseline; WBC = white blood cell count
End point type	Secondary
End point timeframe:	From Baseline until 35 days after the last dose of study drug (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: Participants				
Hemoglobin (g/L), High: Grade (Gr.) 0 (BL) to 0	1	3	2	3
Hemoglobin (g/L), Low: Gr. 0 (BL) to 0	0	0	0	0
Hemoglobin (g/L), Low: Gr. 0 (BL) to 2	0	0	0	0
Hemoglobin (g/L), Low: Gr. 0 (BL) to 3	0	0	0	0
Hemoglobin (g/L), Low: Gr. 1 (BL) to 1	0	2	0	2
Hemoglobin (g/L), Low: Gr. 1 (BL) to 2	0	1	1	0
Hemoglobin (g/L), Low: Gr. 1 (BL) to 3	0	0	1	0
Hemoglobin (g/L), Low: Gr. 2 (BL) to 2	1	0	0	0
Hemoglobin (g/L), Low: Gr. 2 (BL) to 3	0	0	0	0
Hemoglobin (g/L), Low: Gr. 3 (BL) to 3	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), High: Gr. 0 (BL) to 0	1	3	2	3
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 0	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 2	1	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 3	0	0	1	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 0	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 1	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 3	0	0	1	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 2 (BL) to 2	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 2 (BL) to 4	0	1	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 2	0	1	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 3	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 4	0	1	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 4 (BL) to 4	0	0	0	0
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 0	0	2	0	2
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	0	0	0
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 2	0	1	0	0

Neutrophils,Total Abs (10 ⁹ /L),Low: Gr. 0(BL) to 3	1	0	0	1
Neutrophils,Total Abs (10 ⁹ /L),Low: Gr. 0(BL) to 4	0	0	2	0
Neutrophils,Total Abs (10 ⁹ /L),Low: Gr. 2(BL) to 4	0	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 0	0	0	0	1
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	1	0	1
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 2	0	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 3	1	1	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	0	2	1
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 1	0	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 3	0	1	0	0
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 4	0	0	0	0
WBC (10 ⁹ /L), High: Gr. 0 (BL) to 0	1	3	2	3
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 0	0	0	0	2
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	0	0	0
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 2	1	2	0	1
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 3	0	0	2	0
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	0	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 0	0	1	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 1	0	0	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 2	0	0	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 3	0	0	0	0

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Participants				
Hemoglobin (g/L), High: Grade (Gr.) 0 (BL) to 0	4	2	4	5
Hemoglobin (g/L), Low: Gr. 0 (BL) to 0	0	1	0	1
Hemoglobin (g/L), Low: Gr. 0 (BL) to 2	0	1	2	0
Hemoglobin (g/L), Low: Gr. 0 (BL) to 3	0	0	1	0
Hemoglobin (g/L), Low: Gr. 1 (BL) to 1	3	0	1	1
Hemoglobin (g/L), Low: Gr. 1 (BL) to 2	0	0	0	2
Hemoglobin (g/L), Low: Gr. 1 (BL) to 3	0	0	0	0
Hemoglobin (g/L), Low: Gr. 2 (BL) to 2	1	0	0	0
Hemoglobin (g/L), Low: Gr. 2 (BL) to 3	0	0	0	1
Hemoglobin (g/L), Low: Gr. 3 (BL) to 3	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), High: Gr. 0 (BL) to 0	4	2	4	5
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 0	1	0	1	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 2	2	0	1	0

Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 3	0	0	2	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	1	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 0	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 1	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 1 (BL) to 3	1	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 2 (BL) to 2	0	1	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 2 (BL) to 4	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 2	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 3	0	0	0	1
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 3 (BL) to 4	0	0	0	0
Lymphocytes Abs. (10 ⁹ /L), Low: Gr. 4 (BL) to 4	0	0	0	1
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 0	2	0	1	2
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 1	1	0	0	0
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 2	0	1	0	1
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 3	1	0	0	1
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	1	2	1
Neutrophils, Total Abs (10 ⁹ /L), Low: Gr. 2 (BL) to 4	0	0	1	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 0	0	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 1	1	1	1	1
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 2	1	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 3	0	0	0	0
Platelets (10 ⁹ /L), Low: Gr. 0 (BL) to 4	2	1	2	1
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 1	0	0	0	1
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 3	0	0	0	1
Platelets (10 ⁹ /L), Low: Gr. 1 (BL) to 4	0	0	1	1
WBC (10 ⁹ /L), High: Gr. 0 (BL) to 0	4	2	4	5
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 0	2	0	0	1
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 1	0	0	1	2
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 2	0	1	1	0
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 3	1	0	1	0
WBC (10 ⁹ /L), Low: Gr. 0 (BL) to 4	0	1	0	1
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 0	0	0	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 1	1	0	0	0
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 2	0	0	0	1
WBC (10 ⁹ /L), Low: Gr. 1 (BL) to 3	0	0	1	0

Statistical analyses

Secondary: Blood Chemistry Laboratory Test Results Shift Table: Number of Participants by Highest NCI-CTCAE v4.0 Grade at Baseline to Highest Grade Post-Baseline

End point title	Blood Chemistry Laboratory Test Results Shift Table: Number of Participants by Highest NCI-CTCAE v4.0 Grade at Baseline to Highest Grade Post-Baseline
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End point description:

Clinical laboratory tests for blood chemistry parameters were performed at local laboratories and abnormalities (High or Low) were based on local reference ranges. Severity was determined according to NCI-CTCAE v4.0, from Grades 1 (least severe) to 4 (most severe). Grade 0 indicates that results were within the normal range. Not every abnormal laboratory value qualified as an adverse event, only if it met any of the following criteria: clinically significant (per investigator); accompanied by clinical symptoms; resulted in a change in study treatment; or required a medical intervention or a change in concomitant therapy. For multiple post-baseline abnormalities on any given parameter, only the participant's highest grade was reported. BL = Baseline; Blood Gluc., Fast. = blood glucose, fasting; SGOT/AST = serum glutamic-oxaloacetic transaminase/aspartate transaminase; SGPT/ALT = serum glutamic-pyruvic transaminase/alanine transaminase; Triacylglyc. Lipase = triacylglycerol lipase

End point type	Secondary
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End point timeframe:

From Baseline until 35 days after the last dose of study drug (up to 29 months)

End point values	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	2	3
Units: Participants				
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 0	1	3	2	1
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 1	0	0	0	1
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 2	0	0	0	0
Albumin (g/L), Low: Grade (Gr.) 1 (BL) to 1	0	0	0	1
Alkaline Phosphatase (U/L), High: Gr. 0 (BL) to 0	0	3	2	2
Alkaline Phosphatase (U/L), High: Gr. 0 (BL) to 1	0	0	0	0
Alkaline Phosphatase (U/L), High: Gr. 1 (BL) to 1	1	0	0	1
Amylase (U/L), High: Gr. 0 (BL) to 0	1	3	2	3
Amylase (U/L), High: Missing (BL) to Gr. 0	0	0	0	0
Amylase (U/L), High: Gr. 1 (BL) to 1	0	0	0	0
Bilirubin (umol/L), High: Gr. 0 (BL) to 0	1	3	2	3
Bilirubin (umol/L), High: Gr. 0 (BL) to 1	0	0	0	0
Blood Gluc, Fast (mmol/L), High: Missing (BL) to Gr 0	0	0	0	0
Blood Gluc, Fast (mmol/L), High: Gr. 0 (BL) to 1	0	0	1	0

Blood Gluc, Fast (mmol/L), High: Gr. 1 (BL) to 1	0	0	1	0
Blood Gluc, Fast (mmol/L), High: Missing (BL) to Gr 2	1	0	0	0
Blood Gluc., Fast. (mmol/L), High: Missing (All)	0	3	0	3
Blood Gluc, Fast (mmol/L), Low: Gr. 0 (BL) to 0	0	0	2	0
Blood Gluc, Fast (mmol/L), Low: Missing (BL) to Gr 0	1	0	0	0
Blood Gluc., Fast. (mmol/L), Low: Missing (All)	0	3	0	3
Calcium (mmol/L), High: Gr. 0 (BL) to 0	1	3	2	3
Calcium (mmol/L), High: Gr. 1 (BL) to 0	0	0	0	0
Calcium (mmol/L), Low: Gr. 0 (BL) to 0	1	2	2	2
Calcium (mmol/L), Low: Gr. 0 (BL) to 1	0	1	0	0
Calcium (mmol/L), Low: Gr. 0 (BL) to 2	0	0	0	1
Calcium (mmol/L), Low: Gr. 1 (BL) to 1	0	0	0	0
Creatinine (umol/L), High: Gr. 0 (BL) to 0	0	2	0	1
Creatinine (umol/L), High: Gr. 0 (BL) to 1	0	1	2	2
Creatinine (umol/L), High: Gr. 0 (BL) to 3	0	0	0	0
Creatinine (umol/L), High: Gr. 1 (BL) to 0	0	0	0	0
Creatinine (umol/L), High: Gr. 1 (BL) to 1	1	0	0	0
Creatinine (umol/L), High: Gr. 1 (BL) to 2	0	0	0	0
Glucose (mmol/L), High: Gr. 0 (BL) to 0	0	3	0	3
Glucose (mmol/L), High: Missing (BL) to Gr. 0	0	0	1	0
Glucose (mmol/L), High: Gr. 0 (BL) to 3	1	0	0	0
Glucose (mmol/L), High: Missing (All)	0	0	1	0
Glucose (mmol/L), Low: Gr. 0 (BL) to 0	1	2	0	2
Glucose (mmol/L), Low: Missing (BL) to Gr. 0	0	0	1	0
Glucose (mmol/L), Low: Gr. 0 (BL) to 1	0	1	0	1
Glucose (mmol/L), Low: Missing (All)	0	0	1	0
Phosphorus (mmol/L), Low: Gr. 0 (BL) to 0	0	2	2	1
Phosphorus (mmol/L), Low: Missing (BL) to Gr. 0	1	1	0	1
Phosphorus (mmol/L), Low: Missing (BL) to Gr. 2	0	0	0	0
Phosphorus (mmol/L), Low: Missing (All)	0	0	0	1
Potassium (mmol/L), High: Gr. 0 (BL) to 0	0	3	2	2
Potassium (mmol/L), High: Gr. 0 (BL) to 1	1	0	0	1
Potassium (mmol/L), Low: Gr. 0 (BL) to 0	1	2	2	3
Potassium (mmol/L), Low: Gr. 0 (BL) to 2	0	0	0	0
Potassium (mmol/L), Low: Gr. 2 (BL) to 0	0	1	0	0
Potassium (mmol/L), Low: Gr. 2 (BL) to 2	0	0	0	0

SGOT/AST (U/L), High: Gr. 0 (BL) to 0	1	2	2	2
SGOT/AST (U/L), High: Gr. 1 (BL) to 0	0	1	0	1
SGPT/ALT (U/L), High: Gr. 0 (BL) to 0	1	2	1	3
SGPT/ALT (U/L), High: Gr. 1 (BL) to 0	0	1	1	0
SGPT/ALT (U/L), High: Gr. 1 (BL) to 1	0	0	0	0
Sodium (mmol/L), High: Gr. 0 (BL) to 0	1	3	2	3
Sodium (mmol/L), High: Gr. 0 (BL) to 1	0	0	0	0
Sodium (mmol/L), High: Gr. 1 (BL) to 0	0	0	0	0
Sodium (mmol/L), Low: Gr. 0 (BL) to 0	1	3	2	2
Sodium (mmol/L), Low: Gr. 0 (BL) to 1	0	0	0	1
Sodium (mmol/L), Low: Gr. 0 (BL) to 3	0	0	0	0
Sodium (mmol/L), Low: Gr. 1 (BL) to 0	0	0	0	0
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 0	0	3	2	3
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 1	0	0	0	0
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 3	1	0	0	0
Triacylglyc Lipase (U/L),High: Missing(BL) to Gr 0	0	0	0	0
Triacylglyc Lipase (U/L),High: Missing(BL) to Gr 2	0	0	0	0
Uric Acid (umol/L), High: Gr. 0 (BL) to 0	1	3	2	3
Uric Acid (umol/L), High: Missing(BL) to Gr. 0	0	0	0	0
Uric Acid (umol/L), High: Gr. 0 (BL) to 3	0	0	0	0
Uric Acid (umol/L), High: Gr. 3 (BL) to 3	0	0	0	0
Uric Acid (umol/L), High: Gr. 4 (BL) to 3	0	0	0	0

End point values	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	4	5
Units: Participants				
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 0	2	2	4	3
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 1	0	0	0	0
Albumin (g/L), Low: Grade (Gr.) 0 (BL) to 2	1	0	0	1
Albumin (g/L), Low: Grade (Gr.) 1 (BL) to 1	1	0	0	1
Alkaline Phosphatase (U/L), High: Gr. 0 (BL) to 0	3	1	4	3
Alkaline Phosphatase (U/L), High: Gr. 0 (BL) to 1	1	1	0	1
Alkaline Phosphatase (U/L), High: Gr. 1 (BL) to 1	0	0	0	1
Amylase (U/L), High: Gr. 0 (BL) to 0	1	2	3	5
Amylase (U/L), High: Missing (BL) to Gr. 0	2	0	1	0

Amylase (U/L), High: Gr. 1 (BL) to 1	1	0	0	0
Bilirubin (umol/L), High: Gr. 0 (BL) to 0	4	2	3	5
Bilirubin (umol/L), High: Gr. 0 (BL) to 1	0	0	1	0
Blood Gluc, Fast (mmol/L), High: Missing (BL) to Gr 0	0	1	1	1
Blood Gluc, Fast (mmol/L), High: Gr. 0 (BL) to 1	0	0	0	0
Blood Gluc, Fast (mmol/L), High: Gr. 1 (BL) to 1	0	0	0	0
Blood Gluc, Fast (mmol/L), High: Missing (BL) to Gr 2	0	0	0	0
Blood Gluc., Fast. (mmol/L), High: Missing (All)	4	1	3	4
Blood Gluc, Fast (mmol/L), Low: Gr. 0 (BL) to 0	0	0	0	0
Blood Gluc, Fast (mmol/L), Low: Missing (BL) to Gr 0	0	1	1	1
Blood Gluc., Fast. (mmol/L), Low: Missing (All)	4	1	3	4
Calcium (mmol/L), High: Gr. 0 (BL) to 0	3	2	4	5
Calcium (mmol/L), High: Gr. 1 (BL) to 0	1	0	0	0
Calcium (mmol/L), Low: Gr. 0 (BL) to 0	3	2	3	4
Calcium (mmol/L), Low: Gr. 0 (BL) to 1	1	0	1	0
Calcium (mmol/L), Low: Gr. 0 (BL) to 2	0	0	0	0
Calcium (mmol/L), Low: Gr. 1 (BL) to 1	0	0	0	1
Creatinine (umol/L), High: Gr. 0 (BL) to 0	0	0	2	3
Creatinine (umol/L), High: Gr. 0 (BL) to 1	2	2	1	1
Creatinine (umol/L), High: Gr. 0 (BL) to 3	0	0	0	1
Creatinine (umol/L), High: Gr. 1 (BL) to 0	1	0	0	0
Creatinine (umol/L), High: Gr. 1 (BL) to 1	0	0	1	0
Creatinine (umol/L), High: Gr. 1 (BL) to 2	1	0	0	0
Glucose (mmol/L), High: Gr. 0 (BL) to 0	4	2	4	5
Glucose (mmol/L), High: Missing (BL) to Gr. 0	0	0	0	0
Glucose (mmol/L), High: Gr. 0 (BL) to 3	0	0	0	0
Glucose (mmol/L), High: Missing (All)	0	0	0	0
Glucose (mmol/L), Low: Gr. 0 (BL) to 0	4	2	4	4
Glucose (mmol/L), Low: Missing (BL) to Gr. 0	0	0	0	0
Glucose (mmol/L), Low: Gr. 0 (BL) to 1	0	0	0	1
Glucose (mmol/L), Low: Missing (All)	0	0	0	0
Phosphorus (mmol/L), Low: Gr. 0 (BL) to 0	2	0	0	2
Phosphorus (mmol/L), Low: Missing (BL) to Gr. 0	0	0	2	1
Phosphorus (mmol/L), Low: Missing (BL) to Gr. 2	1	0	0	0
Phosphorus (mmol/L), Low: Missing (All)	1	1	2	2
Potassium (mmol/L), High: Gr. 0 (BL) to 0	4	2	4	5
Potassium (mmol/L), High: Gr. 0 (BL) to 1	0	0	0	0

Potassium (mmol/L), Low: Gr. 0 (BL) to 0	3	2	4	3
Potassium (mmol/L), Low: Gr. 0 (BL) to 2	1	0	0	0
Potassium (mmol/L), Low: Gr. 2 (BL) to 0	0	0	0	0
Potassium (mmol/L), Low: Gr. 2 (BL) to 2	0	0	0	2
SGOT/AST (U/L), High: Gr. 0 (BL) to 0	4	2	4	5
SGOT/AST (U/L), High: Gr. 1 (BL) to 0	0	0	0	0
SGPT/ALT (U/L), High: Gr. 0 (BL) to 0	2	2	4	5
SGPT/ALT (U/L), High: Gr. 1 (BL) to 0	0	0	0	0
SGPT/ALT (U/L), High: Gr. 1 (BL) to 1	2	0	0	0
Sodium (mmol/L), High: Gr. 0 (BL) to 0	3	2	4	4
Sodium (mmol/L), High: Gr. 0 (BL) to 1	0	0	0	1
Sodium (mmol/L), High: Gr. 1 (BL) to 0	1	0	0	0
Sodium (mmol/L), Low: Gr. 0 (BL) to 0	4	2	4	3
Sodium (mmol/L), Low: Gr. 0 (BL) to 1	0	0	0	0
Sodium (mmol/L), Low: Gr. 0 (BL) to 3	0	0	0	1
Sodium (mmol/L), Low: Gr. 1 (BL) to 0	0	0	0	1
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 0	2	1	3	4
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 1	0	1	0	0
Triacylglyc. Lipase (U/L), High: Gr. 0 (BL) to 3	0	0	0	0
Triacylglyc Lipase (U/L),High: Missing(BL) to Gr 0	0	0	1	1
Triacylglyc Lipase (U/L),High: Missing(BL) to Gr 2	2	0	0	0
Uric Acid (umol/L), High: Gr. 0 (BL) to 0	2	2	3	4
Uric Acid (umol/L), High: Missing(BL) to Gr. 0	1	0	0	0
Uric Acid (umol/L), High: Gr. 0 (BL) to 3	0	0	0	1
Uric Acid (umol/L), High: Gr. 3 (BL) to 3	0	0	1	0
Uric Acid (umol/L), High: Gr. 4 (BL) to 3	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose until 90 days after the last dose of study treatment (up to 31 months)

Adverse event reporting additional description:

After informed consent but prior to initiation of study drug, only serious AEs caused by protocol-mandated intervention were reported. After initiation of study drug, all AEs were reported until 90 days after the last dose of study drug. After this period, only serious AEs related to prior study drug or Grade 3-4 infections were reported.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).

Reporting group title	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Reporting group title	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 200 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Reporting group title	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²
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Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 150 mg orally in combination with rituximab 375 milligrams per square meter of body surface area (mg/m²) IV for 6 cycles (1 cycle = 28 days).

Reporting group title	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²
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Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in this bridging cohort received induction treatment with idasanutlin 200 mg orally in combination with rituximab 375 mg/m² IV for 6 cycles (1 cycle = 28 days).

Reporting group title	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 100 milligrams (mg) orally in combination with a fixed dose of obinutuzumab 1000 mg intravenously (IV) for 6 cycles (1 cycle = 28 days).

Reporting group title	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory follicular lymphoma (FL) in this non-bridging dose-escalation cohort received induction treatment with idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for 6 cycles (1 cycle = 28 days).

Reporting group title	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg
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Reporting group description:

Participants with relapsed/refractory follicular lymphoma (FL) in this bridging cohort received induction treatment with single-agent obinutuzumab 1000 mg IV for Cycle 1 and then idasanutlin 150 mg orally in combination with a fixed dose of obinutuzumab 1000 mg IV for Cycles 2-6 (1 cycle = 28 days).

Serious adverse events	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
number of deaths (all causes)	0	1	2
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (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			
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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 / 1 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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			
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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	1 / 1 (100.00%)	0 / 3 (0.00%)	0 / 2 (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 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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			
Gastroenteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (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	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 2 (50.00%)
number of deaths (all causes)	2	2	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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			
Acute myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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			
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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			
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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			
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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			
Gastroenteritis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (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 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	2 / 5 (40.00%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			

Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	DLBCL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	DLBCL Non-Bridging: Idasanutlin 200 mg + Obinutuzumab 1000 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	3 / 3 (100.00%)	2 / 2 (100.00%)

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 1 (100.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 1 (100.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Nasal congestion subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Investigations Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Haemophilus test positive subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders			
Dizziness			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Dysgeusia			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Headache			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Memory impairment			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Taste disorder			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Trigeminal neuralgia			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	0 / 2 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 3 (0.00%) 0	2 / 2 (100.00%) 2
Leukopenia			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	2 / 3 (66.67%) 3	0 / 2 (0.00%) 0
Lymphopenia			
subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 3 (33.33%) 1	0 / 2 (0.00%) 0
Neutropenia			
subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	0 / 3 (0.00%) 0	2 / 2 (100.00%) 3
Thrombocytopenia			

subjects affected / exposed occurrences (all)	1 / 1 (100.00%) 1	2 / 3 (66.67%) 2	2 / 2 (100.00%) 2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	2
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 1 (100.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 2 (50.00%)
occurrences (all)	0	1	1

Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	1 / 1 (100.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 1 (100.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-serious adverse events	DLBCL Bridging: Idasanutlin 150 mg + Rituximab 375 mg/m ²	DLBCL Bridging: Idasanutlin 200 mg + Rituximab 375 mg/m ²	FL Non-Bridging: Idasanutlin 100 mg + Obinutuzumab 1000 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	2 / 2 (100.00%)

<p>Vascular disorders</p> <p>Deep vein thrombosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 3 (33.33%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Hot flush</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Hypotension</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>General disorders and administration site conditions</p> <p>Chest pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Fatigue</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 3 (33.33%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 2 (50.00%)</p> <p>1</p>
<p>Oedema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Oedema peripheral</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Pyrexia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 3 (33.33%)</p> <p>1</p>	<p>2 / 4 (50.00%)</p> <p>3</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 2 (0.00%)</p> <p>0</p>
<p>Dyspnoea exertional</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 2 (50.00%)</p> <p>1</p>

Nasal congestion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Investigations Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Haemophilus test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Lipase increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 3	0 / 2 (0.00%) 0
Nervous system disorders			
Dizziness			
subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Dysgeusia			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Headache			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Memory impairment			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Taste disorder			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Trigeminal neuralgia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0	1 / 2 (50.00%) 2
Leukopenia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	0 / 2 (0.00%) 0
Lymphopenia			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Neutropenia			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	4 / 4 (100.00%) 4	1 / 2 (50.00%) 2
Thrombocytopenia			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 2	2 / 4 (50.00%) 2	2 / 2 (100.00%) 2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 3	0 / 4 (0.00%) 0	1 / 2 (50.00%) 4
Nausea			
subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	0 / 4 (0.00%) 0	2 / 2 (100.00%) 6
Constipation			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	1 / 2 (50.00%) 1
Gastrointestinal pain			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Abdominal pain			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Anal inflammation			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Dry mouth			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Dyspepsia			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	1 / 2 (50.00%) 1
Flatulence			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0
Stomatitis			
subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	1 / 2 (50.00%) 1
Vomiting			
subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0	0 / 2 (0.00%) 0

Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Clostridium difficile infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Chronic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Non-serious adverse events	FL Non-Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	FL Bridging: Idasanutlin 150 mg + Obinutuzumab 1000 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	5 / 5 (100.00%)	

<p>Vascular disorders</p> <p>Deep vein thrombosis subjects affected / exposed occurrences (all)</p> <p>Hot flush subjects affected / exposed occurrences (all)</p> <p>Hypotension subjects affected / exposed occurrences (all)</p>	<p>0 / 4 (0.00%) 0</p> <p>0 / 4 (0.00%) 0</p> <p>0 / 4 (0.00%) 0</p>	<p>0 / 5 (0.00%) 0</p> <p>0 / 5 (0.00%) 0</p> <p>1 / 5 (20.00%) 1</p>	
<p>General disorders and administration site conditions</p> <p>Chest pain subjects affected / exposed occurrences (all)</p> <p>Fatigue subjects affected / exposed occurrences (all)</p> <p>Oedema subjects affected / exposed occurrences (all)</p> <p>Oedema peripheral subjects affected / exposed occurrences (all)</p> <p>Pain subjects affected / exposed occurrences (all)</p> <p>Pyrexia subjects affected / exposed occurrences (all)</p>	<p>0 / 4 (0.00%) 0</p> <p>3 / 4 (75.00%) 8</p> <p>0 / 4 (0.00%) 0</p>	<p>0 / 5 (0.00%) 0</p> <p>1 / 5 (20.00%) 1</p> <p>0 / 5 (0.00%) 0</p> <p>0 / 5 (0.00%) 0</p> <p>1 / 5 (20.00%) 1</p> <p>0 / 5 (0.00%) 0</p>	
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough subjects affected / exposed occurrences (all)</p> <p>Dyspnoea exertional subjects affected / exposed occurrences (all)</p>	<p>0 / 4 (0.00%) 0</p> <p>0 / 4 (0.00%) 0</p>	<p>2 / 5 (40.00%) 2</p> <p>0 / 5 (0.00%) 0</p>	

Nasal congestion subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	
Rhinitis allergic subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Investigations Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Blood bilirubin increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 5 (0.00%) 0	
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Haemophilus test positive subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Lipase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	1 / 5 (20.00%) 1	
Cardiac disorders Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	
Tachycardia			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Taste disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences (all)	1	0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 4 (75.00%)	2 / 5 (40.00%)	
occurrences (all)	3	3	
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	
occurrences (all)	2	1	
Lymphopenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	
occurrences (all)	1	1	
Neutropenia			
subjects affected / exposed	3 / 4 (75.00%)	3 / 5 (60.00%)	
occurrences (all)	10	4	
Thrombocytopenia			

subjects affected / exposed occurrences (all)	4 / 4 (100.00%) 7	4 / 5 (80.00%) 6	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 8	3 / 5 (60.00%) 5	
Nausea			
subjects affected / exposed occurrences (all)	3 / 4 (75.00%) 8	5 / 5 (100.00%) 11	
Constipation			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	2 / 5 (40.00%) 3	
Gastrointestinal pain			
subjects affected / exposed occurrences (all)	2 / 4 (50.00%) 3	0 / 5 (0.00%) 0	
Abdominal pain			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Anal inflammation			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Dry mouth			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 5 (20.00%) 1	
Dyspepsia			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Flatulence			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Stomatitis			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 5 (0.00%) 0	
Vomiting			
subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	3 / 5 (60.00%) 4	

<p>Skin and subcutaneous tissue disorders</p> <p>Eczema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Night sweats</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Skin ulcer</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>Muscle spasms</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Musculoskeletal chest pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Arthritis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 5 (20.00%)</p> <p>1</p>	
<p>Groin pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Myalgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Pain in extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Infections and infestations</p> <p>Clostridium difficile infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	
<p>Upper respiratory tract infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 4 (25.00%)</p> <p>1</p>	<p>0 / 5 (0.00%)</p> <p>0</p>	

Herpes zoster			
subjects affected / exposed	1 / 4 (25.00%)	0 / 5 (0.00%)	
occurrences (all)	1	0	
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Chronic sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	2 / 4 (50.00%)	0 / 5 (0.00%)	
occurrences (all)	2	0	
Sinusitis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	
occurrences (all)	1	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 5 (20.00%)	
occurrences (all)	1	1	
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 5 (20.00%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 5 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 October 2015	Key changes in the protocol amendment (Version 2): -Revised inclusion criterion #4 and deleted inclusion criterion #5; -Revised definition of a dose-limiting toxicity (DLT); -Added the IND number; -Changed the Medical Monitor; -Corrected the start of obinutuzumab regimen at Month 2, instead of at Month 1, during the maintenance treatment for patients with follicular lymphoma (FL). Patient enrollment commenced under Protocol Version 2.
12 February 2016	Key changes in the protocol amendment (Version 3): -Clarified patients to receive maintenance treatment; -Updated the number of study sites to 25; -Updated inclusion criteria; -Added uncontrolled GI conditions as part of the uncontrolled concomitant disease exclusion criteria; -Corrected concomitant therapy reporting period; -Clarified the modified Lugano criteria for designation of PET-CT–based PR; -Added an exploratory efficacy endpoint to analyze efficacy based on TP53 status; -Clarified that diarrhea (Grade ≥ 2), neutropenia (Grade ≥ 3), and thrombocytopenia (Grade ≥ 3 or Grade ≥ 2 if associated with hemorrhage or bleeding) are considered AESI; -Clarified criteria for patient replacement during the dose escalation phase; -Updated the dose-limiting toxicity criteria that Grade 3 diarrhea that responds to adequate therapy within 48 hours (instead of 72 hours) is not considered as a DLT; -Removed need for collection of human anti-human antibody samples; -Clarified that obinutuzumab PK samples are to be collected at Cycle 6 Day 1; -Clarified that Roche Clinical Repository sample collection is needed at Cycle 1 Day 5; -Clarified that deaths attributed to progression of lymphoma during follow-up is to be reported on the Study Completion/Early Discontinuation eCRF instead of being reported as an adverse event; -Added monthly pregnancy testing; -Included additional ECG collection timepoints (coupled to PK sampling) and instructions to enhance safety monitoring; -Clarified idasanutlin dose reduction steps; -Clarified management of other non-hematologic Grade 3 or 4 toxicities in patients who have had 0-2 prior dose reductions; -Updated dose and guidelines for loperamide usage; -Clarified prohibited therapy and exclusion criteria for anticoagulant treatment; -Updated background on idasanutlin for clarity; -Updated prohibited therapy list with OATP-1B1/3 transporter substrates as part of the prohibited therapy; -Harmonized obinutuzumab language among the obinutuzumab program.
02 March 2017	Key changes in the protocol amendment (Version 4): -Changed study design to add bridging cohort(s) in the dose escalation phase. Patients with DLBCL to receive idasanutlin in combination with rituximab after the MTD of idasanutlin is identified in combination with obinutuzumab. Updated background, rationale, study objectives, study design, eligibility criteria, and statistical plan; -Updated obinutuzumab exposure data; -Updated idasanutlin data based on the idasanutlin Investigator’s Brochure, Version 9 (November 2016, cutoff 13 September 2016); - Added idasanutlin as post-induction treatment in the expansion phase; exploratory efficacy endpoint added accordingly; -Clarified guidelines for the second and subsequent infusion of obinutuzumab; -Updated the classification of second malignancies; -Added Grade ≥ 2 Clostridium difficile infection as AESI; - Added an alternative regimen with obinutuzumab given alone at Cycle 1, followed by obinutuzumab in combination with idasanutlin from Cycles 2 to 6 (dose escalation phase for FL patients); -Modified the DLT definition to include any Grade 5 toxicities; -Updated the DLT criterion regarding thrombocytopenia; - Introduced a new DLT criterion regarding changes in liver enzyme; -Treatment Regimen and Expansion Phase (Part 2) sections; -Clarified exclusion criteria regarding the use of strong and moderate CYP3A inhibitors, strong and moderate CYP3A inducers, and CYP2C8 and OATP1B1/3 substrates; -Updated guidance on prohibited and cautionary therapies and their respective washout periods; -Clarified the dose reduction guidance; -Updated guidance regarding liver function test criteria -Updated guidance on the allowed time window for PK sample collection; -Defined interim analysis; -Clarified rescreening of patients.

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.

Due to the overall modest benefit achieved with the maximum tolerated dose during the dose escalation phase, the Sponsor decided not to open the expansion phase and terminated the study. Consequently, some planned analyses could not be performed.

Notes: