Clinical trial results:
A phase I/II study of lutetium (177Lu)-lilotomab satetraxetan (Betalutin®) antibody-radionuclide-conjugate for treatment of relapsed non-Hodgkin lymphoma.

Summary

EudraCT number	2011-000033-36
Trial protocol	SE GB IT CZ AT FR ES HR HU IE DK FI DE NL BE
Global end of trial date	27 October 2022

Results information

Result version number	v1 (current)
This version publication date	16 April 2023
First version publication date	16 April 2023

Trial information

Trial identification

Sponsor protocol code	LYMRIT-37-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01796171
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Nordic Nanovector
Sponsor organisation address	Kjelsåsveien 168B, N-0884 , Oslo, Norway,
Public contact	Information Desk, Nordic Nanovector ASA, +47 22183301, mail@nordicnanovector.com
Scientific contact	Information Desk, Nordic Nanovector ASA, +47 22183301, mail@nordicnanovector.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	31 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 October 2022
Global end of trial reached?	Yes
Global end of trial date	27 October 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Part A:
Phase I (Arms 1, 2, 3, 4, and 5): To define MTD of Betalutin
Phase IIa: To explore tumour response rates in patients receiving Betalutin.

Part B Phase IIb
Overall response rate

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice (GCP) guidelines and local law requirements. A Safety Review Committee reviewed and monitored the safety of participants on on ongoing basis and at pre-defined timepoints, to recommend appropriate actions at the pre-defined timepoints of dose adjustment and to support the identification of the MTD

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 December 2012
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	Netherlands: 1
Country: Number of subjects enrolled	Norway: 39
Country: Number of subjects enrolled	Poland: 6
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Sweden: 4
Country: Number of subjects enrolled	United Kingdom: 45
Country: Number of subjects enrolled	Croatia: 3
Country: Number of subjects enrolled	Austria: 2
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Czechia: 13
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	Finland: 5
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Ireland: 8
Country: Number of subjects enrolled	Italy: 6

Country: Number of subjects enrolled	Australia: 6
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Turkey: 3
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	United States: 7
Country: Number of subjects enrolled	Singapore: 1
Worldwide total number of subjects	191
EEA total number of subjects	125

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)	64
From 65 to 84 years	124
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were screened in the 2-4 weeks before receiving rituximab (according to protocol version). They received rituximab on Days -28 and -21 or Day -14 prior to treatment with lilotomab and Betalutin on Day 0.

Period 1

Period 1 title	Enrolled
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

Note: Parts A and C were non-randomised and open label . Part B was blinded for the first 47 participants, participants were randomly allocated to 40/15 or 100/20. Following an interim analysis, dosing with 100/20 was stopped and all subsequent dosing was non randomised.

Arms

Arm title	All participants enrolled

Arm description: -

Arm type	Pre-treatment

No investigational medicinal product assigned in this arm

Number of subjects in period 1	All participants enrolled
Started	191
Completed	190
Not completed	1
Death	1

Period 2

Period 2 title	Received rituximab
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

Note: Parts A and C were non-randomised and open label . Part B was blinded for the first 47 participants, participants were randomly allocated to 40/15 or 100/20. Following an interim analysis,

dosing with 100/20 was stopped and all subsequent dosing was non randomised.

Arms

Arm title	All participants treated

Arm description: -

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

Dosage and administration details:

Participants received 375 mg/m2 rituximab pre-treatment by intravenous infusion either 28 and 21 days or 14 days prior to lilotomab and Betalutin on Day 0

Number of subjects in period 2	All participants treated
Started	190
Completed	187
Not completed	3
Consent withdrawn by subject	1
Adverse event, non-fatal	2

Period 3

Period 3 title	Received lilotomab and Betalutin
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

Note: Parts A and C were non-randomised and open label . Part B was blinded for the first 47 participants, participants were randomly allocated to 40/15 or 100/20. Following an interim analysis, dosing with 100/20 was stopped and all subsequent dosing was non randomised.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A Arm 1 40 mg/10 MBq

Arm description:

10 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:	
Participants received 10 MBq/kg Betalutin by slow bolus intravenous injection	
Investigational medicinal product name	Lilotomab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 40 mg lilotomab by intravenous infusion	
Arm title	Part A Arm 1 40 mg/15 MBq
Arm description:	
15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use
Dosage and administration details:	
Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection	
Investigational medicinal product name	Lilotomab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 40 mg lilotomab by intravenous infusion	
Arm title	Part A Arm 1 40 mg/20 MBq
Arm description:	
20 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use
Dosage and administration details:	
Participants received 20 MBq/kg Betalutin by slow bolus intravenous injection	
Investigational medicinal product name	Lilotomab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 40 mg lilotomab by intravenous infusion	
Arm title	Part A Arm 2 No pre-dosing/10 MBq
Arm description:	
10 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Arm type	Experimental

Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 10 MBq/kg Betalutin by slow bolus intravenous injection

Arm title	Part A Arm 2 No pre-dosing/15 MBq

Arm description:

15 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection

Arm title	Part A Arm 3 RTX pre-dosing/15 MBq

Arm description:

15 MBq/kg Betalutin with rituximab pre-dosing. Participants were also pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 375 mg/m2 based on body surface area

Arm title	Part A Arm 4 100mg/m2/15 MBq

Arm description:

15 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 100 mg/m2 lilotomab by intravenous infusion

Arm title	Part A Arm 4 100mg/m2/20 MBq

Arm description:

20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 20 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 100 mg/m2 lilotomab by intravenous infusion

Arm title	Part A Arm 5 60 mg/m2/20 MBq

Arm description:

20 MBq/kg Betalutin with 60 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 20 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 60 mg/m2 lilotomab by intravenous infusion

Arm title	Part B 40 mg/15 MBq

Arm description:

15 MBq/kg Betalutin with 40 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental

Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 40 mg lilotomab by intravenous infusion

Arm title	Part B 100 mg/m2/20 MBq

Arm description:

20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 20 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 100 mg/m2 lilotomab by intravenous infusion

Arm title	Part B 40 mg/12.5 MBq

Arm description:

12.5 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 12.5 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 40 mg lilotomab by intravenous infusion

Arm title	Part C 40 mg/15 MBq

Arm description:

15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Arm type	Experimental
Investigational medicinal product name	Betalutin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

Participants received 15 MBq/kg Betalutin by slow bolus intravenous injection

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

Dosage and administration details:

Participants received 40 mg lilotomab by intravenous infusion

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: The baseline period for reporting demographics and baseline variables is the patients who received lilotomab and Betalutin. Rituximab pre-treatment was also given. The number enrolled includes all patients allocated to treatment. One was randomised but not treated and 3 received rituximab pre-treatment but not lilotomab and Betalutin so these 4 are not in the baseline period

Number of subjects in period 3[2]	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq
Started	4	36	3
Completed	4	35	3
Not completed	0	1	0
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Death	-	-	-
Start of further anticancer therapy	-	-	-
Progressive disease	-	1	-
Sponsor decision	-	-	-

Number of subjects in period 3[2]	Part A Arm 2 No pre-dosing/10 MBq	Part A Arm 2 No pre-dosing/15 MBq	Part A Arm 3 RTX pre-dosing/15 MBq
Started	1	2	3
Completed	1	2	3
Not completed	0	0	0
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Death	-	-	-
Start of further anticancer therapy	-	-	-
Progressive disease	-	-	-

Sponsor decision	-	-	-

Number of subjects in period 3[2]	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100mg/m2/20 MBq	Part A Arm 5 60 mg/m2/20 MBq
Started	3	18	4
Completed	3	18	3
Not completed	0	0	1
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Death	-	-	-
Start of further anticancer therapy	-	-	1
Progressive disease	-	-	-
Sponsor decision	-	-	-

Number of subjects in period 3[2]	Part B 40 mg/15 MBq	Part B 100 mg/m2/20 MBq	Part B 40 mg/12.5 MBq
Started	72	28	9
Completed	61	25	8
Not completed	11	3	1
Physician decision	5	1	1
Consent withdrawn by subject	1	1	-
Death	2	-	-
Start of further anticancer therapy	1	1	-
Progressive disease	-	-	-
Sponsor decision	2	-	-

Number of subjects in period 3[2]	Part C 40 mg/15 MBq
Started	4
Completed	4
Not completed	0
Physician decision	-
Consent withdrawn by subject	-
Death	-
Start of further anticancer therapy	-
Progressive disease	-
Sponsor decision	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The baseline period for reporting demographics and baseline variables is the patients who received lilotomab and Betalutin. Rituximab pre-treatment was also given. The number enrolled includes all patients allocated to treatment. One was randomised but not treated and 3 received rituximab pre-treatment but not lilotomab and Betalutin so these 4 are not in the baseline period

Period 4

Period 4 title	Follow-up period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A Arm 1 40 mg/10 MBq

Arm description:

Follow-up of participants receiving 40 mg lilotomab and 10 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 1 40 mg/15 MBq

Arm description:

Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 1 40 mg/20 MBq

Arm description:

Follow-up of participants receiving 40 mg lilotomab and 20 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 2 10 MBq No pre-dosing

Arm description:

Follow-up of participants receiving 10 MBq/kg Betalutin with no pre-dosing

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 2 15 MBq/No pre-dosing

Arm description:

Follow-up of participants receiving 15 MBq/kg Betalutin with no pre-dosing

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 3 RTX pre-dosing/15 MBq

Arm description:

Follow-up of participants receiving rituximab pre-dosing and 15 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 4 100mg/m2/15 MBq

Arm description:

Follow-up of participants receiving 100 mg/m2 lilotomab and 15 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 4 100 mg/m2/20 MBq

Arm description:

Follow-up of participants receiving 100 mg/m2 lilotomab and 20 MBq/kg Betalutin

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Part A Arm 5 60 mg/m2/20 MBq

Arm description:	
Follow-up of participants receiving 60 mg/m2 lilotomab and 20 MBq/kg Betalutin	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B 40 mg/15 MBq
Arm description:	
Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B 100 mg/m2/20 MBq
Arm description:	
Follow-up of participants receiving 100 mg/m2 lilotomab and 20 MBq/kg Betalutin	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B 40 mg/12.5 MBq
Arm description:	
Follow-up of participants receiving 40 mg lilotomab and 12.5 MBq/kg Betalutin	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part C 40 mg/15 MBq
Arm description:	
Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 4	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq
Started	4	35	3
Completed	0	5	1
Not completed	4	30	2
Physician decision	-	2	-
Consent withdrawn by subject	-	1	-
Death	-	-	-
Participant transferred to other hospital	-	1	-
Start of further anticancer therapy	4	25	2
Progressive disease	-	1	-
Sponsor decision	-	-	-

Number of subjects in period 4	Part A Arm 2 10 MBq No pre-dosing	Part A Arm 2 15 MBq/No pre-dosing	Part A Arm 3 RTX pre-dosing/15 MBq
Started	1	2	3
Completed	0	0	0
Not completed	1	2	3
Physician decision	-	-	-
Consent withdrawn by subject	-	-	1

Death	-	-	-
Participant transferred to other hospital	-	-	-
Start of further anticancer therapy	1	2	2
Progressive disease	-	-	-
Sponsor decision	-	-	-

Number of subjects in period 4	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100 mg/m2/20 MBq	Part A Arm 5 60 mg/m2/20 MBq
Started	3	18	3
Completed	1	0	1
Not completed	2	18	2
Physician decision	-	-	-
Consent withdrawn by subject	-	-	-
Death	1	-	-
Participant transferred to other hospital	-	-	-
Start of further anticancer therapy	1	15	2
Progressive disease	-	3	-
Sponsor decision	-	-	-

Number of subjects in period 4	Part B 40 mg/15 MBq	Part B 100 mg/m2/20 MBq	Part B 40 mg/12.5 MBq
Started	61	25	8
Completed	0	0	0
Not completed	61	25	8
Physician decision	4	-	-
Consent withdrawn by subject	3	1	-
Death	17	9	1
Participant transferred to other hospital	-	-	-
Start of further anticancer therapy	-	-	-
Progressive disease	-	-	-
Sponsor decision	37	15	7

Number of subjects in period 4	Part C 40 mg/15 MBq
Started	4
Completed	0
Not completed	4
Physician decision	1
Consent withdrawn by subject	-
Death	-
Participant transferred to other hospital	-
Start of further anticancer therapy	-
Progressive disease	-

Sponsor decision	3

Baseline characteristics

Reporting groups

Reporting group title	Part A Arm 1 40 mg/10 MBq
Reporting group description:	
10 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 1 40 mg/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 1 40 mg/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 2 No pre-dosing/10 MBq
Reporting group description:	
10 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 2 No pre-dosing/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 3 RTX pre-dosing/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with rituximab pre-dosing. Participants were also pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 4 100mg/m2/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 4 100mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 5 60 mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 60 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 40 mg/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 40 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 100 mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 40 mg/12.5 MBq
Reporting group description:	
12.5 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part C 40 mg/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	

Reporting group values	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq
Number of subjects	4	36	3
Age categorical			
Age at the time of informed consent			
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	11	1
From 65-84 years	2	25	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	1	19	0
Male	3	17	3

Reporting group values	Part A Arm 2 No pre-dosing/10 MBq	Part A Arm 2 No pre-dosing/15 MBq	Part A Arm 3 RTX pre-dosing/15 MBq
Number of subjects	1	2	3
Age categorical			
Age at the time of informed consent			
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)	0	0	0
From 65-84 years	1	2	2
85 years and over	0	0	1
Gender categorical Units: Subjects			
Female	0	1	2
Male	1	1	1

Reporting group values	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100mg/m2/20 MBq	Part A Arm 5 60 mg/m2/20 MBq
Number of subjects	3	18	4
Age categorical			
Age at the time of informed consent			
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	4	1
From 65-84 years	2	14	3
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	0	8	2
Male	3	10	2

Reporting group values	Part B 40 mg/15 MBq	Part B 100 mg/m2/20 MBq	Part B 40 mg/12.5 MBq
Number of subjects	72	28	9
Age categorical			
Age at the time of informed consent			
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)	26	9	4
From 65-84 years	45	19	4
85 years and over	1	0	1
Gender categorical			
Units: Subjects			
Female	43	16	3
Male	29	12	6

Reporting group values	Part C 40 mg/15 MBq	Total	
Number of subjects	4	187	
Age categorical			
Age at the time of informed consent			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	3	62	
From 65-84 years	1	122	
85 years and over	0	3	

Gender categorical Units: Subjects			
Female	3	98	
Male	1	89	

End points

End points reporting groups

Reporting group title	All participants enrolled
Reporting group description: -	
Reporting group title	All participants treated
Reporting group description: -	
Reporting group title	Part A Arm 1 40 mg/10 MBq
Reporting group description:	
10 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 1 40 mg/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 1 40 mg/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 2 No pre-dosing/10 MBq
Reporting group description:	
10 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 2 No pre-dosing/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 3 RTX pre-dosing/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with rituximab pre-dosing. Participants were also pre-treated with rituximab on Days -28 and -21 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 4 100mg/m2/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 4 100mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part A Arm 5 60 mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 60 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 40 mg/15 MBq
Reporting group description:	
15 MBq/kg Betalutin with 40 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 100 mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0	
Reporting group title	Part B 40 mg/12.5 MBq
Reporting group description:	
12.5 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on	

Day - 14 prior to lilotomab and Betalutin on Day 0

Reporting group title	Part C 40 mg/15 MBq

Reporting group description:

15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14 prior to lilotomab and Betalutin on Day 0

Reporting group title	Part A Arm 1 40 mg/10 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 10 MBq/kg Betalutin

Reporting group title	Part A Arm 1 40 mg/15 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin

Reporting group title	Part A Arm 1 40 mg/20 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 20 MBq/kg Betalutin

Reporting group title	Part A Arm 2 10 MBq No pre-dosing

Reporting group description:

Follow-up of participants receiving 10 MBq/kg Betalutin with no pre-dosing

Reporting group title	Part A Arm 2 15 MBq/No pre-dosing

Reporting group description:

Follow-up of participants receiving 15 MBq/kg Betalutin with no pre-dosing

Reporting group title	Part A Arm 3 RTX pre-dosing/15 MBq

Reporting group description:

Follow-up of participants receiving rituximab pre-dosing and 15 MBq/kg Betalutin

Reporting group title	Part A Arm 4 100mg/m2/15 MBq

Reporting group description:

Follow-up of participants receiving 100 mg/m2 lilotomab and 15 MBq/kg Betalutin

Reporting group title	Part A Arm 4 100 mg/m2/20 MBq

Reporting group description:

Follow-up of participants receiving 100 mg/m2 lilotomab and 20 MBq/kg Betalutin

Reporting group title	Part A Arm 5 60 mg/m2/20 MBq

Reporting group description:

Follow-up of participants receiving 60 mg/m2 lilotomab and 20 MBq/kg Betalutin

Reporting group title	Part B 40 mg/15 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin

Reporting group title	Part B 100 mg/m2/20 MBq

Reporting group description:

Follow-up of participants receiving 100 mg/m2 lilotomab and 20 MBq/kg Betalutin

Reporting group title	Part B 40 mg/12.5 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 12.5 MBq/kg Betalutin

Reporting group title	Part C 40 mg/15 MBq

Reporting group description:

Follow-up of participants receiving 40 mg lilotomab and 15 MBq/kg Betalutin

Primary: Part A Phase I: To define the Maximum Tolerated Dose (MTD)

End point title	Part A Phase I: To define the Maximum Tolerated Dose

End point description:

To define the MTD of Betalutin as assessed by the number of participants with dose limiting toxicities (DLTs) in Part A Phase I

Note: the DLT in reporting group 7 (40 mg lilotomab/15 MBq/kg Betalutin) meeting the criterion 'failure of platelets or neutrophils to recover to Grade 1 by 12 weeks after treatment' was identified retrospectively after dose escalation had occurred

End point type	Primary

End point timeframe:

12 weeks after Betalutin

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 study followed a standard 3+3 design to determine the MTD of Betalutin. No statistical analysis was appropriate in this small number of participants
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data for all participants in Phase Ia are reported. This part of the study assessed the MTD for expansion in Phase IIa

End point values	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq	Part A Arm 2 No pre-dosing/10 MBq
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	3	1
Units: Number of participants	0	1	3	0

End point values	Part A Arm 2 No pre-dosing/15 MBq	Part A Arm 3 RTX pre-dosing/15 MBq	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100mg/m2/20 MBq
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	3	6
Units: Number of participants	2	1	1	1

End point values	Part A Arm 5 60 mg/m2/20 MBq			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: Number of participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Part A Phase IIa: To explore tumour response rates in FL

End point title	Part A Phase IIa: To explore tumour response rates in FL[3][4]

End point description:

To explore tumour response rates in Phase IIa patients with follicular lymphoma receiving Betalutin according to Cheson et al, 2007 (combining morphological and metabolic responses) based on evaluation of CT scan images including PET/CT imaging (and bone marrow biopsy if applicable).

End point type	Primary

End point timeframe:

3 months to 5 years

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The purpose of Part IIa was to select doses for further investigation in Part B. Both doses were selected, therefore a statistical analysis was not considered appropriate in this small number of participants
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The study was conducted in several parts. The endpoint reports results for all participants in Part IIa with FL as encouraging efficacy was seen in these participants. Data in Phase IIa participants without FL were not summarised

End point values	Part A Arm 1 40 mg/15 MBq	Part A Arm 4 100mg/m2/20 MBq		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	9		
Units: Number of participants				
Complete remission	7	2		
Partial remission	5	6		
Stable disease	3	1		
Progressive disease	3	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Phase IIb

End point title	Part B: Phase IIb[5][6]

End point description:

Overall response rate defined as the number of participants with a best response of complete remission or partial remission at any time according to Cheson, 2014.

End point type	Primary

End point timeframe:

3 months to 5 years

Notes:

[5] - 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: Following an interim analysis, the 40/15 dose only was selected for evaluation, therefore no statistical analysis was deemed appropriate
[6] - 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: The study was conducted in several parts. The endpoint reports results for all participants in Part B

End point values	Part B 40 mg/15 MBq	Part B 100 mg/m2/20 MBq		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	28		
Units: Number of participants	28	9		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events were collected up to 12 weeks after Betalutin administration. Treatment-related adverse events were collected up to 5 years (end of the study)

Adverse event reporting additional description:

Adverse events are reported for all participants who received rituximab, lilotomab and Betalutin from the time of lilotomab and Betalutin administration (Day 0) onwards

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Part A Arm 1 40 mg/10 MBq

Reporting group description:

10 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 1 40 mg/15 MBq

Reporting group description:

15 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 1 40 mg/20 MBq

Reporting group description:

20 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 2 No pre-dosing/10 MBq

Reporting group description:

10 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 2 No pre-dosing/15 MBq

Reporting group description:

15 MBq/kg Betalutin with no pre-dosing. Participants were pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 3 RTX pre-dosing/15 MBq

Reporting group description:

15 MBq/kg Betalutin with rituximab pre-dosing. Participants were also pre-treated with rituximab on Days -28 and -21

Reporting group title	Part A Arm 4 100mg/m2/15 MBq

Reporting group description:

15 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14

Reporting group title	Part A Arm 4 100mg/m2/20 MBq

Reporting group description:

20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14

Reporting group title	Part A Arm 5 60 mg/m2/20 MBq

Reporting group description:

20 MBq/kg Betalutin with 60 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14

Reporting group title	Part B and C 40 mg/15 MBq

Reporting group description:

15 MBq/kg Betalutin with 40 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14

Reporting group title	Part B 100 mg/m2/20 MBq
Reporting group description:	
20 MBq/kg Betalutin with 100 mg/m2 lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14	

Reporting group title	Part B 40 mg/12.5 MBq
Reporting group description:	
12.5 MBq/kg Betalutin with 40 mg lilotomab pre-dosing. Participants were pre-treated with rituximab on Day - 14	

Serious adverse events	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	6 / 36 (16.67%)	2 / 3 (66.67%)
number of deaths (all causes)	2	10	0
number of deaths resulting from adverse events	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chronic myelomonocytic leukaemia	Additional description: Occurrences related to treatment have been recorded as those related to Betalutin		
subjects affected / exposed	1 / 4 (25.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 4 (25.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Sternal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Radiation pneumonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileal perforation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative dictionary used:			

MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A Arm 2 No pre-dosing/10 MBq	Part A Arm 2 No pre-dosing/15 MBq	Part A Arm 3 RTX pre-dosing/15 MBq
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events		0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chronic myelomonocytic leukaemia	Additional description: Occurrences related to treatment have been recorded as those related to Betalutin		
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung adenocarcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal neoplasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Endometrial cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Sternal fracture			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileal perforation			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100mg/m2/20 MBq	Part A Arm 5 60 mg/m2/20 MBq
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	2	6	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chronic myelomonocytic leukaemia	Additional description: Occurrences related to treatment have been recorded as those related to Betalutin		
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal neoplasm			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
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			
Malaise			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Sternal fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
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			
Ileal perforation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
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			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
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			
Nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B and C 40 mg/15 MBq	Part B 100 mg/m2/20 MBq	Part B 40 mg/12.5 MBq
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 76 (15.79%)	7 / 28 (25.00%)	0 / 9 (0.00%)
number of deaths (all causes)	23	11	1
number of deaths resulting from adverse events	2	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Chronic myelomonocytic leukaemia	Additional description: Occurrences related to treatment have been recorded as those related to Betalutin		
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal neoplasm			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Breast cancer			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (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
Endometrial cancer			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Malaise			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			

subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Sternal fracture			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Presyncope			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (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			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (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

Neutropenia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ileal perforation			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (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
Renal and urinary disorders			
Nephrolithiasis			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
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			
Pharyngitis			

subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
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	1 / 76 (1.32%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (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
Urinary tract infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection bacterial			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rhinovirus infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Part A Arm 1 40 mg/10 MBq	Part A Arm 1 40 mg/15 MBq	Part A Arm 1 40 mg/20 MBq
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	36 / 36 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 4 (25.00%)	3 / 36 (8.33%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Follicular lymphoma			

subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	2 / 36 (5.56%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	5 / 36 (13.89%)	3 / 3 (100.00%)
occurrences (all)	0	5	3
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	3 / 36 (8.33%)	3 / 3 (100.00%)
occurrences (all)	0	3	3
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	4 / 36 (11.11%)	2 / 3 (66.67%)
occurrences (all)	0	4	2
Lymphocyte count decreased			

subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	3 / 3 (100.00%)
occurrences (all)	0	2	3
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Cardiac murmur			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Road traffic accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dose calculation error			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	3 / 36 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Dysgeusia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	2 / 4 (50.00%)	20 / 36 (55.56%)	0 / 3 (0.00%)
occurrences (all)	2	23	0
Thrombocytopenia			
subjects affected / exposed	1 / 4 (25.00%)	19 / 36 (52.78%)	0 / 3 (0.00%)
occurrences (all)	1	19	0
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	14 / 36 (38.89%)	0 / 3 (0.00%)
occurrences (all)	1	15	0
Lymphopenia			
subjects affected / exposed	1 / 4 (25.00%)	9 / 36 (25.00%)	0 / 3 (0.00%)
occurrences (all)	1	10	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 36 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 4 (25.00%)	4 / 36 (11.11%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Diarrhoea			

subjects affected / exposed	1 / 4 (25.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Mouth haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
Abdominal pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin burning sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo positional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			

subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypermobility syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	4 / 36 (11.11%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	3 / 36 (8.33%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 36 (2.78%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	2 / 36 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gout			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 4 (0.00%)	0 / 36 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A Arm 2 No pre-dosing/10 MBq	Part A Arm 2 No pre-dosing/15 MBq	Part A Arm 3 RTX pre-dosing/15 MBq
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Follicular lymphoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	3 / 3 (100.00%)
occurrences (all)	0	2	3
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	3 / 3 (100.00%)
occurrences (all)	0	1	3
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood creatine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dose calculation error			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	2 / 2 (100.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue coated			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema multiforme			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo positional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypermobility syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gout			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 1 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A Arm 4 100mg/m2/15 MBq	Part A Arm 4 100mg/m2/20 MBq	Part A Arm 5 60 mg/m2/20 MBq
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	16 / 18 (88.89%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	2 / 4 (50.00%)
occurrences (all)	0	2	2
Follicular lymphoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rales			

subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
White blood cell count decreased			
subjects affected / exposed	2 / 3 (66.67%)	3 / 18 (16.67%)	2 / 4 (50.00%)
occurrences (all)	3	3	2
Neutrophil count decreased			
subjects affected / exposed	2 / 3 (66.67%)	3 / 18 (16.67%)	1 / 4 (25.00%)
occurrences (all)	2	3	1
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	4 / 18 (22.22%)	0 / 4 (0.00%)
occurrences (all)	1	4	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 3 (33.33%)	4 / 18 (22.22%)	1 / 4 (25.00%)
occurrences (all)	1	4	2
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dose calculation error			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	5 / 18 (27.78%)	0 / 4 (0.00%)
occurrences (all)	0	5	0
Thrombocytopenia			

subjects affected / exposed	0 / 3 (0.00%)	4 / 18 (22.22%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lymphocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	3
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Mouth haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Tongue coated			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Erythema multiforme			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo positional			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Renal impairment			
subjects affected / exposed	1 / 3 (33.33%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypermobility syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	2 / 18 (11.11%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 18 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Lower respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 18 (11.11%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 18 (5.56%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Decreased appetite			

subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gout			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 3 (0.00%)	0 / 18 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B and C 40 mg/15 MBq	Part B 100 mg/m2/20 MBq	Part B 40 mg/12.5 MBq
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 76 (80.26%)	22 / 28 (78.57%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Follicular lymphoma			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 76 (3.95%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Haematoma			
subjects affected / exposed	1 / 76 (1.32%)	1 / 28 (3.57%)	1 / 9 (11.11%)
occurrences (all)	1	2	1
Hot flush			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 76 (10.53%)	3 / 28 (10.71%)	2 / 9 (22.22%)
occurrences (all)	8	3	2
Influenza like illness			

subjects affected / exposed	1 / 76 (1.32%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Asthenia			
subjects affected / exposed	4 / 76 (5.26%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
Axillary pain			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 76 (2.63%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Pain			
subjects affected / exposed	1 / 76 (1.32%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 76 (3.95%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	3	2	0
Dysphonia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Rales			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	2 / 76 (2.63%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	5 / 76 (6.58%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Dyspnoea exertional			

alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	1 / 28 (3.57%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Investigations			
White blood cell count decreased			
subjects affected / exposed	2 / 76 (2.63%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	2	2	0
Neutrophil count decreased			
subjects affected / exposed	5 / 76 (6.58%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	7	1	0
Platelet count decreased			
subjects affected / exposed	8 / 76 (10.53%)	3 / 28 (10.71%)	0 / 9 (0.00%)
occurrences (all)	8	3	0
Lymphocyte count decreased			
subjects affected / exposed	3 / 76 (3.95%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Blood creatine increased			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	1
Blood lactate dehydrogenase decreased			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Cardiac murmur			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			

subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Road traffic accident			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dose calculation error			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 76 (3.95%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Dysgeusia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	3 / 76 (3.95%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Hypersomnia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	12 / 76 (15.79%)	3 / 28 (10.71%)	3 / 9 (33.33%)
occurrences (all)	16	3	4
Thrombocytopenia			
subjects affected / exposed	13 / 76 (17.11%)	3 / 28 (10.71%)	3 / 9 (33.33%)
occurrences (all)	13	4	3
Leukopenia			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	4 / 76 (5.26%)	1 / 28 (3.57%)	1 / 9 (11.11%)
occurrences (all)	6	1	1
Anaemia			

subjects affected / exposed	11 / 76 (14.47%)	5 / 28 (17.86%)	2 / 9 (22.22%)
occurrences (all)	12	5	2
Leukocytosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocytosis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	9 / 76 (11.84%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	9	2	0
Diarrhoea			
subjects affected / exposed	7 / 76 (9.21%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	7	2	0
Mouth haemorrhage			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	5 / 76 (6.58%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	5	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	4 / 76 (5.26%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Tongue coated			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 76 (2.63%)	2 / 28 (7.14%)	1 / 9 (11.11%)
occurrences (all)	2	2	1
Paraesthesia oral			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Erythema multiforme			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	5 / 76 (6.58%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Skin burning sensation			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alopecia			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Eczema			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vertigo positional			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 76 (2.63%)	4 / 28 (14.29%)	1 / 9 (11.11%)
occurrences (all)	2	5	1
Back pain			
subjects affected / exposed	5 / 76 (6.58%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	6	2	0
Pain in extremity			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Hypermobility syndrome			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	3 / 76 (3.95%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	2 / 76 (2.63%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 76 (1.32%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 76 (0.00%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 76 (1.32%)	0 / 28 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
COVID-19			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	4 / 76 (5.26%)	0 / 28 (0.00%)	1 / 9 (11.11%)
occurrences (all)	4	0	1
Infection			
alternative dictionary used: MedDRA 25.1			
subjects affected / exposed	0 / 76 (0.00%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 76 (0.00%)	1 / 28 (3.57%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	3 / 76 (3.95%)	2 / 28 (7.14%)	0 / 9 (0.00%)
occurrences (all)	3	2	0
Gout			
alternative dictionary used: MedDRA 25.1			

subjects affected / exposed occurrences (all)	0 / 76 (0.00%) 0	0 / 28 (0.00%) 0	1 / 9 (11.11%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 September 2012	Version 4.0 In the Phase I part of the study, participants were to receive two infusions of 250 mg/m2 rituximab (the first on Day -7 and the second within 4 hours before Betalutin injection on Day 0). The first participant was to receive a sentinel dose of 10 MBq/kg Betalutin; subsequent participants were to be enrolled following a '3+3' design with escalating doses of Betalutin. Dose expansion at the maximum tolerated dose (MTD) was then to be performed in the Phase IIa part of the study (referred to as Phase IIa Arm 1).
25 March 2013	Version 5.0 • The pre-treatment/pre-dosing regimen was amended to two pre-treatment infusions of 375 mg/m2 rituximab (the first on Day -28 and the second on Day -21) plus pre-dosing with 40 mg lilotomab within 4 hours of Betalutin injection on Day 0) • Additional participants were included at the 10 MBq/kg Betalutin dose level
11 March 2014	Version 6.0 • Smaller dose de-escalation steps of 5 MBq/kg were implemented (i.e. from 20 MBq/kg to 15 MBq/kg based on the study status at the time of implementation of this amendment) • A Quality of Life assessment (FACT-Lym) was introduced in Part A Phase IIa
18 February 2015	Version 6B • Phase I Arm 2 was introduced to investigate the effect of omitting pre-dosing with lilotomab • The Dose Limiting Toxicity (DLT) definition was updated
26 November 2015	Version 7.0 • The following Phase I arms were introduced: Arm 3 (to investigate pre-dosing with rituximab on Day 0), Arm 4 (pre-dosing with 100 mg/m2 lilotomab on Day 0) and Arm 5 (pre-dosing with a combination of both rituximab and 100 mg/m2 lilotomab on Day 0). The starting dose of Betalutin in all three cohorts was 15 MBq/kg, with the possibility of escalation to 17.5 MBq/kg or 20 MBq/kg. Participants continued to be eligible for enrolment into the 10 MBq/kg cohort of Arm 2 until this version of the protocol was approved given the prolonged partial remission (PR) participants had experienced with this dose of Betalutin in Arm 1 and the likely reduction in haematological toxicities seen in this arm with the 15 MBq/kg dose of Betalutin • The rituximab pre-treatment regimen introduced in Version 5.0 was amended to a single infusion of 375 mg/m2 on Day -14 for Phase I Arms 3, 4 and 5 • The inclusion criterion requiring participants to have CD37 positive tumours was removed. No validated commercial assay of CD37 expression in tumour samples was available (testing of CD37 expression at screening was continued) and a total of 99.5% of the lymphoma tumour tissues tested with the available assay were positive for expression of CD37. Removing this criterion prevented delay in the treatment of participants whilst tumour tissue was tested for little or no potential benefit

04 July 2016	Version 8.0 • The dose of Betalutin was capped at the dose corresponding to a body weight of 130 kg
28 November 2016	Version 9.0 • Enrolment was continued following the interim analysis in expansion of Phase IIa Arm 1 • A second Phase IIa expansion cohort with a further 10 to 15 participants was added to Arm 4 with the 100/20 treatment regimen and pre-treatment with rituximab on Day -14 (assuming acceptable tolerability in the first three to six participants) • The lilotomab dose to be tested in Phase I Arm 5 was changed to 60 mg/m2. Rituximab pre dosing on Day 0 (in combination with lilotomab) was removed since review of data from Arm 3 showed no benefit of rituximab pre-dosing on Day 0. The intermediate escalation step of 17.5 MBq/kg was also removed from Arm 5 • DLTs in Phase I Arm 1 were re-evaluated using the DLT criteria that were applied for Arms 2, 3, 4, 5 and Phase IIa (under Protocol Version 6B), to harmonise the assessment of the safety data of all enrolled participants/treatment arms • Exclusion criterion 2 was amended to allow the treatment of participants with a screening platelet count of 100 to 150×109/L in the Phase II Arm 4, depending on safety review of participants with a screening platelet count >150×109/L treated with 20 MBq/kg Betalutin and 100 mg/m2 lilotomab by the Safety Review Committee (SRC)
04 July 2017	Version 10.0 • The number of participants enrolled in Phase IIa Arm 1 was increased from 24 to 30 as an additional six participants had provided informed consent and started screening procedures at the time the original enrolment target of 24 participants was reached and it was considered unethical by the Sponsor to withhold treatment
27 October 2017	Version 11.0 • Following decision by the SRC the dose of Betalutin in Arm 5 was fixed at 20 MBq/kg • Part B (PARADIGME) was added to the study, with a Phase IIb randomised design to compare the two recommended doses for Phase II identified and confirmed in Part A Phase I and Phase IIa, respectively. Up to 130 additional participants were to be treated with either the "40/15" or "100/20" treatment regimens to further delineate the risk: benefit profile of these treatment regimens in a population with relapsed, rituximab/anti CD20 refractory follicular lymphoma (FL) • The primary assessment of tumour responses was updated to Cheson et al, 2014 by Independent review Committee (IRC) • The DLT definition was updated • A clarification was added that survival information and potential long-term toxicity information would continue to be collected on withdrawn participants unless consent was withdrawn • Immunogenicity assessments to measure the anti-drug antibody (ADA) response in Part B were added • Biobanking of tumour samples and peripheral blood samples for future analysis was added

22 October 2018	Version 12.0 • Magnetic resonance imaging (MRI) was added as an alternative to contrast enhanced computed tomography (CT) for disease assessments • Statistical methods were updated to include the method for comparing the ORR between the two treatment regimens in Part B • Three country-specific addenda were added: Germany: Additional pregnancy testing was added in the 3 days prior to rituximab administration and also at Months 2, 4, 5, 7, 8, 9 and 11. In-patient hospitalisation for 48 hours after Betalutin injection and confirmation of CD37 antigen positive FL before Betalutin administration, were required France: Clarification was made that the source documentation for the collection of participant ethnic origin and race, would be the electronic case report form (eCRF) (these data would not be recorded in patient medical file) and consent would be taken prior to collection of these data. Further clarifications relating to blood sampling for deoxyribonucleic acid (DNA) extraction and human leukocyte antigen (HLA) typing, clarification of biobanking, analysis and destruction Ireland and Norway: Pregnancy testing was mandated monthly after Betalutin injection until 12 months after Betalutin injection (or withdrawal)
13 March 2020	Version 13.0 • The Part B interim analysis information was updated. The overall response rate (ORR) boundary of 40% was made non-binding and for guidance only when deciding whether to terminate treatment regimens. The majority (75%) of the 48 participants enrolled in Part B at the time of the protocol amendment had exhausted all treatment options, and 64% had received prior bendamustine (which had been reported in a Phase II study investigating duvelisib in participants with refractory B-cell indolent NHL to be associated with an ORR of 39% [Flinn et al, 2019]). A number of enrolled participants were also refractory to phosphoinositide 3-kinase (PI3K) inhibitors. Since the participant population appeared more refractory than initially anticipated, the ORR cut-off of 40% was considered too strict
31 July 2020	Version 14.0 • The participant population for Part B was redefined: The platelet threshold for inclusion was reduced from ≥150×109/L to ≥100×109/L to allow enrolment of a more representative population of patients with FL Participants with a prior autologous stem cell transplant (SCT) could be included if at least 2 years had elapsed since transplantation, and they had been without Grade ≥1 graft versus host disease for at least 8 weeks (the requirement relating to graft versus host disease was subsequently removed in Version 15.0) • The 100/20 treatment regimen was terminated at the recommendation of the SRC following the Part B interim analysis. Part B was to continue with the 40/15 treatment regimen only, with a lower Betalutin dose for the sub-populations with the lower platelet threshold and/or prior autologous-SCT: 12.5 MBq/kg for participants with prior autologous-SCT and but platelets ≥150×109/L 12.5 MBq/kg for participants without prior autologous-SCT and platelets 100 to <150×109/L 10 MBq/kg for participants with prior autologous-SCT and platelets 100 to <150×109/L • Additional SRC meetings were included to review the first three participants enrolled in the following sub-populations (i) lower platelet threshold, (ii) autologous-SCT and (iii) lower platelet threshold and autologous-SCT, after all three participants in each sub population had been followed for at least 6 weeks • Single-photon emission computed tomography/computed tomography (SPECT/CT) dosimetry was no longer required at sites collecting pharmacokinetic samples, except for participants entering Part B from sites in Germany and in other agreed sites. The Part B exploratory objectives were updated accordingly • Statistical analysis of pharmacokinetics was added • The country-specific addendum for Germany was amended to clarify that the participants must have confirmed positive CD37 FL before receiving Betalutin

26 January 2021	Version 15.0 was not submitted and was superseded by the next amendments Versions 15.1 to 15.4 • Part C was added to better characterise the pharmacokinetics of Betalutin and total lilotomab antibodies of the 40/15 treatment regimen • Specific rules for dose determination following a "3+3" design were added in the three sub populations with the lower platelet threshold and/or prior autologous-SCT introduced in Version 14.0 • The Part B objectives were updated to delineate between the randomised and non randomised sub-parts and additional objectives relating to complete response rate (CRR) and duration of complete response (DoCR) were added. Clarifications that Part B efficacy endpoints would be assessed by IRC and the Investigator were added where required • The Part B sample size was updated to reflect termination of dosing with the 100/20 treatment regimen and set a hypothesis and sample size for assessment of the 40/15 treatment regimen selected for further development • Flexibility was included to the screening period and the possibility of performing study visits without key assessments as non-hospital visits due to the COVID-19 pandemic • The different study periods were better clarified, up to 3 months, from 6 to 12 months and thereafter with clear separation of what is required during follow-up until disease progression or start of further anti-cancer therapy (extensive follow-up involving hospital visits) versus after disease progression or further therapy (limited follow-up which may be conducted by telephone). Starting further therapy was removed as an option for withdrawal from the study as participants were to enter limited (long term) follow-up when they had disease progression or start another cancer treatment (whichever comes first). This follow up allowed for long term toxicities of Betalutin, to be captured and managed • The country-specific addendum for Ireland and Norway was updated for pregnancy tests
19 February 2021	Version 15.1 Haematology testing prior to rituximab infusion was added in order to verify the applicable eligibility criteria
06 April 2021	Version 15.2 - Specific to US only: The definitions of duration of response (DoR) and duration of complete response (DoCR) were updated at the request of the US Food and Drug Administration (FDA) to include death due to any cause
28 July 2021	Version 15.3: Applicable to France only Amendment to Version 15.1 following feedback from the regulatory authority in France: Scheduled safety reviews and dose decision making criteria were added for participants in Part C
28 July 2021	Version 15.4: Applicable to US only Amendment to Version 15.2 to remove the requirement for a negative human anti-mouse antibody (HAMA) test result at screening as: The likelihood of a participant having received prior murine antibody therapy was very low given the low number of approved murine-based therapies on the market The recorded screen failure rate in the study due to pre-existing HAMA was low at the time of the amendment Effective mitigation and precautionary measures were in place in the unlikely event of hypersensitivity reactions caused by pre-existing HAMAs reacting with successively administered murine monoclonal antibodies (lilotomab/Betalutin)

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.

Participants were enrolled to protocol Version 4.0 and later. The overall study design of protocol Version 4.0 and the subsequent amendments are identified in the protocol amendments section

Notes: