Clinical trial results:
A Phase 1b/2 Open Label Umbrella Study of Sasanlimab Combined With Anti-Cancer Therapies Targeting Multiple Molecular Mechanisms in Participants with Non-Small Cell Lung Cancer (NSCLC)

Summary

EudraCT number	2020-002829-28
Trial protocol	BE NL
Global end of trial date	28 October 2024

Results information

Result version number	v1 (current)
This version publication date	31 October 2025
First version publication date	31 October 2025

Trial information

Trial identification

Sponsor protocol code	B8011011

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04585815
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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	07 March 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 October 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Substudy A (SSA): 1- To assess the dose limiting toxicity (DLT) rate and estimate the maximum tolerated dose (MTD) of sasanlimab in combination with encorafenib and binimetinib to determine the recommended Phase 2 dose (RP2D) for the combination. 2- To assess the durable objective response rate (ORR) of sasanlimab in combination with encorafenib and binimetinib.
Substudy B (SSB): 1-) To assess the DLT rate and estimate the MTD of sasanlimab in combination with axitinib and SEATGT to determine the RP2D for the combination. 2-) To assess the ORR of sasanlimab in combination with axitinib and SEATGT.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 6
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	United States: 23
Worldwide total number of subjects	34
EEA total number of subjects	1

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)	13
From 65 to 84 years	21
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Sub-study A (SSA) was planned to be conducted in 2 parts: Phase 1b and Phase 2. Due to a business decision, Phase 2 was not initiated, hence no participants were enrolled for Phase 2 of SSA. Sub-study B (SSB) was conducted in 2 parts: Phase 1b and Phase 2.

Pre-assignment

Screening details:

57 participants signed informed consent and 34 participants were enrolled in the study. Of these 34 participants, 13 were enrolled in Sub-study A and 21 in Sub-study B (9 in Phase [Ph] 1b and 12 in Phase 2).

Period 1

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

Blinding implementation details:

There was no blinding.

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini (45mg)

Arm description:

Participants with non-small cell lung cancer (NSCLC) with BRAFV600 mutations were administered a single dose of sasanlimab 300 milligrams (mg) subcutaneously on Day 1 of each cycle along with once daily (QD) oral dose of 300 mg encorafenib and twice daily (BID) oral dose of 45 mg binimetinib during each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 300 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 300 mg administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	Binimetinib 45 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Binimetinib 45 mg orally twice daily.

Investigational medicinal product name	Encorafenib 300 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received Encorafenib 300 mg orally once daily.

Arm title	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini (45mg)

Arm description:

Participants with NSCLC with BRAFV600 mutations were administered a single dose of sasanlimab 300 mg subcutaneously on Day 1 of each cycle along with QD oral dose of 450 mg encorafenib and BID oral dose of 45 mg binimetinib during each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 300 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 300 mg administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	Binimetinib 45 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Binimetinib 45 mg orally twice daily.

Investigational medicinal product name	Encorafenib 450 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Participants received Encorafenib 450 mg orally once daily.

Arm title	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)

Arm description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg every 3 weeks (Q3W) subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle during each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Axitinib 5mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Axitinib 5mg orally twice daily.

Investigational medicinal product name	Sasanlimab 225 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 225 mg Q3W administered subcutaneously on Day 1 of each cycle.

Arm title	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)

Arm description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W intravenous (IV) infusion of 1 milligram per kilogram (mg/kg)

SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 225 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 225 mg Q3W administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	SEA-TGT 1 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a single dose of SEA-TGT 1 mg/kg administered intravenously on Day 1 of each cycle.

Investigational medicinal product name	Axitinib 5mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Axitinib 5mg orally twice daily.

Arm title	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Arm description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with low programmed death ligand - 1 (PD-L1) levels tumor proportion score (TPS)-49 percent (%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 225 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 225 mg Q3W administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	SEA-TGT 1 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a single dose of SEA-TGT 1 mg/kg administered intravenously on Day 1 of each cycle.

Investigational medicinal product name	Axitinib 5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:

Participants received Axitinib 5mg orally twice daily.

Arm title	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Arm description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with high PD-L1 (TPS greater than or equal to [>=]50%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA + TGT on Day 1 of each cycle during each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 225 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 225 mg Q3W administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	Axitinib 5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Axitinib 5mg orally twice daily.

Investigational medicinal product name	SEA-TGT 1 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a single dose of SEA-TGT 1 mg/kg administered intravenously on Day 1 of each cycle.

Arm title	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Arm description:

Participants with NSCLC who received 1 or 2 lines of therapy for advanced/metastatic NSCLC and whose disease has progressed on prior PD-1/ PD-L1 therapy and who have PD-L1 TPS >= 1% were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and 1 mg/kg IV infusion Q3W SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Sasanlimab 225 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received a single dose of sasanlimab 225 mg Q3W administered subcutaneously on Day 1 of each cycle.

Investigational medicinal product name	SEA-TGT 1 mg/kg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received a single dose of SEA-TGT 1 mg/kg administered intravenously on Day 1 of each cycle.

Investigational medicinal product name	Axitinib 5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received Axitinib 5mg orally twice daily.

Number of subjects in period 1	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini(45mg)	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini(45mg)	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)
Started	4	9	3
Completed	0	0	0
Not completed	4	9	3
Adverse event, serious fatal	-	2	-
Consent withdrawn by subject	1	-	-
Physician decision	-	-	-
Global deterioration of health status	-	1	-
Adverse event, non-fatal	1	4	-
Study terminated by sponsor	1	1	-
Unspecified	1	-	-
Progressive disease	-	1	3

Number of subjects in period 1	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)
Started	6	3	2
Completed	0	0	0
Not completed	6	3	2
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	1	-	1
Physician decision	1	1	-
Global deterioration of health status	1	-	-
Adverse event, non-fatal	-	-	-
Study terminated by sponsor	-	-	-

Unspecified	-	-	-
Progressive disease	2	2	1

Number of subjects in period 1	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)
Started	7
Completed	0
Not completed	7
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Physician decision	-
Global deterioration of health status	-
Adverse event, non-fatal	2
Study terminated by sponsor	-
Unspecified	-
Progressive disease	5

Baseline characteristics

Reporting groups

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini (45mg)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) with BRAFV600 mutations were administered a single dose of sasanlimab 300 milligrams (mg) subcutaneously on Day 1 of each cycle along with once daily (QD) oral dose of 300 mg encorafenib and twice daily (BID) oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini (45mg)

Reporting group description:

Participants with NSCLC with BRAFV600 mutations were administered a single dose of sasanlimab 300 mg subcutaneously on Day 1 of each cycle along with QD oral dose of 450 mg encorafenib and BID oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg every 3 weeks (Q3W) subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W intravenous (IV) infusion of 1 milligram per kilogram (mg/kg) SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with low programmed death ligand - 1 (PD-L1) levels tumor proportion score (TPS)-49 percent (%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with high PD-L1 (TPS greater than or equal to [>=]50%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA + TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who received 1 or 2 lines of therapy for advanced/metastatic NSCLC and whose disease has progressed on prior PD-1/ PD-L1 therapy and who have PD-L1 TPS >= 1% were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and 1 mg/kg IV infusion Q3W SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group values	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini (45mg)	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)
Number of subjects	4	9	3

Age categorical Units: Subjects			
In Utero	0	0	0
Preterm newborn infants (gestional 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
12 - 17 years	0	0	0
Adults (18 - 64 years)	1	5	0
From 65 - 84 years	3	4	3
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	67.50	61.56	68.33
standard deviation	± 8.74	± 8.66	± 1.53
Gender categorical Units: Subjects			
Male	1	6	2
Female	3	3	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	4	8	3
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
Black or African American	1	0	0
Asian	1	5	0
White	2	4	3

Reporting group values	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)
Number of subjects	6	3	2
Age categorical Units: Subjects			
In Utero	0	0	0
Preterm newborn infants (gestional 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
12 - 17 years	0	0	0
Adults (18 - 64 years)	1	1	0
From 65 - 84 years	5	2	2
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	69.50	69.33	67.50

standard deviation	± 7.34	± 7.51	± 2.12

Gender categorical Units: Subjects			
Male	5	2	1
Female	1	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	3	2
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
Black or African American	2	1	0
Asian	1	0	0
White	3	2	2

Reporting group values	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Total	
Number of subjects	7	34	
Age categorical Units: Subjects			
In Utero	0	0	
Preterm newborn infants (gestional 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	
12 - 17 years	0	0	
Adults (18 - 64 years)	5	13	
From 65 - 84 years	2	21	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	62.57		
standard deviation	± 7.07	-	
Gender categorical Units: Subjects			
Male	5	22	
Female	2	12	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	2	
Not Hispanic or Latino	6	32	
Unknown or Not Reported	0	0	
Race (NIH/OMB) Units: Subjects			
Black or African American	0	4	

Asian	0	7	
White	7	23	

End points

End points reporting groups

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini (45mg)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) with BRAFV600 mutations were administered a single dose of sasanlimab 300 milligrams (mg) subcutaneously on Day 1 of each cycle along with once daily (QD) oral dose of 300 mg encorafenib and twice daily (BID) oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini (45mg)

Reporting group description:

Participants with NSCLC with BRAFV600 mutations were administered a single dose of sasanlimab 300 mg subcutaneously on Day 1 of each cycle along with QD oral dose of 450 mg encorafenib and BID oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg every 3 weeks (Q3W) subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W intravenous (IV) infusion of 1 milligram per kilogram (mg/kg) SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with low programmed death ligand - 1 (PD-L1) levels tumor proportion score (TPS)-49 percent (%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who were treatment-naïve for advanced/metastatic disease with high PD-L1 (TPS greater than or equal to [>=]50%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA + TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who received 1 or 2 lines of therapy for advanced/metastatic NSCLC and whose disease has progressed on prior PD-1/ PD-L1 therapy and who have PD-L1 TPS >= 1% were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and 1 mg/kg IV infusion Q3W SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Primary: Phase 1b of Sub-Study A: Percentage of Participants With Dose-Limiting Toxicities (DLT)

End point title	Phase 1b of Sub-Study A: Percentage of Participants With Dose-Limiting Toxicities (DLT)[1][2]

End point description:

DLT=AEs in DLT observation period(OP) related to any study intervention: Grade(G)4 neutropenia;

thrombocytopenia/ anemia; febrile neutropenia; neutropenic infection;G3 thrombocytopenia with bleeding. Any G>=3 toxicity (except transient G3 fatigue, local reactions/ headache that resolved to G<=1/baseline; G3 nausea, vomiting controlled within 72 hrs, G3 hypertension controlled by medical therapy [MT], G3 diarrhea that improved to G<=2 within 72 hrs,G3 skin toxicity that resolved to G<=1 in <7 days after MT, G3 endocrinopathies controlled by MT and tumors flare); Non-hematologic G3 lab abnormality [LA]/ any G4 LA;ALT/AST>3*ULN (normal at baseline) or >3*ULN and doubling baseline (>ULN at baseline) and associated with total bilirubin(TB) >2*ULN; or ALT/AST >5*ULN; or TB>3*ULN. DLT-evaluable analysis set included all participants who received at least 1 dose of study treatment in Phase 1b and eitherexperienced DLT during DLT-observation period/ completed DLT-observation period without DLT.

End point type	Primary

End point timeframe:

Day 1 up to Day 28 of Cycle 1

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: No statistical analyses have been planned

[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: The end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Percentage of participants				
number (not applicable)	0	33.3		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1b of Sub-Study B: Percentage of Participants With DLT

End point title	Phase 1b of Sub-Study B: Percentage of Participants With

End point description:

DLT=AEs in DLT OP related to any study intervention: Grade(G)4 neutropenia; thrombocytopenia/ anemia; febrile neutropenia; neutropenic infection; G3 thrombocytopenia with bleeding. Any G>=3 toxicity (except transient G3 fatigue, local reactions/ headache that resolved to G<=1/baseline; G3 nausea, vomiting controlled within 72 hrs, G3 hypertension controlled by MT, G3 diarrhea that improved to G<=2 within 72 hrs,G3 skin toxicity that resolved to G<=1 in <7 days after MT, G3 endocrinopathies controlled by MT and tumors flare); Non-hematologic G3 LA/ any G4 LA;ALT/AST>3*ULN (normal at baseline) or >3*ULN and doubling baseline (>ULN at baseline) and associated with total bilirubin >2*ULN; or ALT/ AST >5*ULN; or TB>3*ULN. DLT-evaluable analysis set included all participants who received at least 1 dose of study treatment in Phase 1b and either experienced DLT during DLT-observation period/ completed DLT-observation period without DLT.

End point type	Primary

End point timeframe:

Day 1 up to Day 21 of Cycle 1

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: No statistical analyses have been planned

[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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Percentage of participants				
number (not applicable)	0	16.7		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2 Sub-Study B: Objective Response Rate

End point title	Phase 2 Sub-Study B: Objective Response Rate[5][6]

End point description:

ORR was defined as percentage of participants with confirmed CR or PR according to RECIST v1.1 based on investigator assessment, from the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy. CR was defined as complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 millimeter [mm]). PR was defined as greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. PD was defined as 20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in the sum was observed during therapy), with a minimum absolute increase of 5 mm. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Primary

End point timeframe:

From the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy (maximum of 21 months)

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: No statistical analyses have been planned

[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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Percentage of participants				
median (confidence interval 95%)	33.3 (0.8 to 90.6)	0.0 (0.0 to 84.2)	14.3 (0.4 to 57.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Number of Participants With Adverse Events (AEs) Graded According to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0

End point title	Phase 1b of Sub-Study A: Number of Participants With Adverse Events (AEs) Graded According to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0[7]

End point description:

An AE was any untoward medical occurrence in a participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs was graded by the investigator according to NCI CTCAE grade 1 to 5 version 5.0; where Grade 1=mild, Grade 2=moderate, Grade 3=severe, Grade 4=life-threatening and Grade 5=death. Safety analysis set includes all participants who receive at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 38.66 months; maximum follow-up approximately 39.66 months)

Notes:

[7] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Participants				
Grade 1	1	0		
Grade 2	0	2		
Grade 3	3	4		
Grade 4	0	2		
Grade 5	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Number of Participants With Shift from Baseline in Hematology Parameters Values Based on CTCAE V5.0

End point title	Phase 1b of Sub-Study A: Number of Participants With Shift

	from Baseline in Hematology Parameters Values Based on CTCAE V5.0[8]

End point description:

Hematology parameters included: anemia, hemoglobin increased, leukocytosis, lymphocyte count decreased, lymphocyte count increased, leukocytosis, neutrophil count decreased, platelet count decreased, white blood cell decreased. Laboratory abnormalities were graded as per NCI- CTCAE v 5.0 where, grade(G) 0= non-missing lab value that does not meet either of G1 through 4 criteria, G1=mild, G2=moderate, G3=severe and G4= life-threatening or disabling. Baseline is defined as the last assessment prior to the date/time of the first dose of study treatment. Number of participants with shift from baseline in hematology parameters by grades (as per CTCAE version 5.0) with non-zero values were reported. Safety analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 38.66 months; maximum follow-up approximately 39.66 months)

Notes:

[8] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Participants				
Anemia: Grade 0 to 0	3	2		
Anemia: Grade 0 to 1	0	2		
Anemia: Grade 0 to 2	0	1		
Anemia: Grade 1 to 1	0	4		
Anemia: Grade 1 to 2	1	0		
Hemoglobin increased: Grade 0 to 0	4	8		
Hemoglobin increased: Grade 0 to 1	0	1		
Leukocytosis: Grade 0 to 0	4	9		
Lymphocyte count decreased: Grade 0 to 0	2	3		
Lymphocyte count decreased: Grade 0 to 1	1	1		
Lymphocyte count decreased: Grade 0 to 2	1	2		
Lymphocyte count decreased: Grade 0 to 4	0	1		
Lymphocyte count decreased: Grade 1 to 2	0	1		
Lymphocyte count decreased: Grade 2 to 2	0	1		
Lymphocyte count increased: Grade 0 to 0	4	9		
Neutrophil count decreased: Grade 0 to 0	4	7		
Neutrophil count decreased: Grade 0 to 1	0	1		
Neutrophil count decreased: Grade 0 to 2	0	1		
Platelet count decreased: Grade 0 to 0	4	7		
Platelet count decreased: Grade 0 to 1	0	1		
Platelet count decreased: Grade 1 to 1	0	1		

White blood cell decreased: Grade 0 to 0	3	8		
White blood cell decreased: Grade 0 to 1	1	0		
White blood cell decreased: Grade 2 to 2	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Number of Participants With Shift from Baseline in Chemistry Parameters Values Based on CTCAE V5.0

End point title	Phase 1b of Sub-Study A: Number of Participants With Shift from Baseline in Chemistry Parameters Values Based on CTCAE V5.0[9]

End point description:

Chemistry parameters included: alanine aminotransferase (ALT) increase, alkaline phosphatase (ALP) increased, aspartate aminotransferase (AST) increased, blood bilirubin increased, creatinine phosphokinase (CPK) increased, chronic kidney disease (CKD), creatinine increased, hypercalcemia, hyperkalemia, hypermagnesemia, hypernatremia, hypoalbuminemia, hypocalcemia, hypoglycemia, hypokalemia, hypomagnesemia, hyponatremia, lipase increased, serum amylase increased. Chemistry abnormalities were graded as per NCI- CTCAE v 5.0 where, grade(G) 0= non-missing lab value that does not meet either of G1 through 4 criteria, G1=mild, G2=moderate, G3=severe and G4= life-threatening or disabling. Baseline is defined as the last assessment prior to the date/time of the first dose of study treatment. Number of participants with shift from baseline in chemistry parameters by grades (as per CTCAE version 5.0) with non-zero values were reported. Safety analysis set.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 38.66 months; maximum follow-up approximately 39.66 months)

Notes:

[9] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Participants				
Alanine aminotransferase increased: Grade 0 to 0	2	2		
Alanine aminotransferase increased: Grade 0 to 1	2	2		
Alanine aminotransferase increased: Grade 0 to 2	0	2		
Alanine aminotransferase increased: Grade 0 to 3	0	3		
Alkaline phosphatase increased: Grade 0 to 0	1	3		
Alkaline phosphatase increased: Grade 0 to 1	0	2		

Alkaline phosphatase increased: Grade 0 to 2	0	1		
Alkaline phosphatase increased: Grade 1 to 0	2	2		
Alkaline phosphatase increased: Grade 1 to 2	1	0		
Aspartate aminotransferase increased:Grade0 to 0	2	2		
Aspartate aminotransferase increased:Grade0 to 1	2	4		
Aspartate aminotransferase increased:Grade0 to 2	0	1		
Aspartate aminotransferase increased:Grade0 to 3	0	1		
Aspartate aminotransferase increased:Grade1 to 2	0	1		
Blood bilirubin increased: Grade 0 to 0	4	8		
Blood bilirubin increased: Grade 0 to 3	0	1		
CPK increased: Grade 0 to 0	2	4		
CPK increased: Grade 0 to 1	2	1		
CPK increased: Grade 0 to 2	0	2		
CPK increased: Grade 0 to 3	0	1		
CPK increased: Grade 0 to 4	0	1		
Chronic kidney disease: Grade 0 to 0	1	3		
Chronic kidney disease: Grade 0 to 1	0	1		
Chronic kidney disease: Grade 0 to 2	2	3		
Chronic kidney disease: Grade 1 to 1	1	1		
Chronic kidney disease: Grade 2 to 2	0	1		
Creatinine increased: Grade 0 to 0	1	6		
Creatinine increased: Grade 0 to 1	2	2		
Creatinine increased: Grade 0 to 2	1	1		
Hypercalcemia: Grade 0 to 0	3	4		
Hypercalcemia: Grade 0 to 1	1	5		
Hyperkalemia: Grade 0 to 0	4	8		
Hyperkalemia: Grade 0 to 1	0	1		
Hypermagnesemia: Grade 0 to 0	4	8		
Hypermagnesemia: Grade 0 to 1	0	1		
Hypernatremia: Grade 0 to 0	4	8		
Hypernatremia: Grade 0 to 1	0	1		
Hypoalbuminemia: Grade 0 to 0	2	3		
Hypoalbuminemia: Grade 0 to 1	1	3		
Hypoalbuminemia: Grade 0 to 2	0	1		
Hypoalbuminemia: Grade 0 to 3	1	0		
Hypoalbuminemia: Grade 1 to 1	0	1		
Hypoalbuminemia: Grade 1 to 2	0	1		
Hypocalcemia: Grade 0 to 0	4	7		
Hypocalcemia: Grade 0 to 1	0	2		
Hypoglycemia: Grade 0 to 0	4	7		
Hypoglycemia: Grade 0 to 1	0	1		
Hypoglycemia: Grade 1 to 0	0	1		
Hypokalemia: Grade 0 to 0	4	7		
Hypokalemia: Grade 0 to 2	0	1		
Hypokalemia: Grade 0 to 3	0	1		
Hypomagnesemia: Grade 0 to 0	4	8		

Hypomagnesemia: Grade 0 to 1	0	1		
Hyponatremia: Grade 0 to 0	3	5		
Hyponatremia: Grade 0 to 1	0	1		
Hyponatremia: Grade 0 to 3	0	1		
Hyponatremia: Grade 1 to 0	1	0		
Hyponatremia: Grade 1 to 3	0	2		
Lipase increased: Grade 0 to 0	1	5		
Lipase increased: Grade 0 to 1	2	3		
Lipase increased: Grade 0 to 2	1	1		
Serum amylase increased: Grade 0 to 0	4	7		
Serum amylase increased: Grade 0 to 3	0	1		
Serum amylase increased: Grade 1 to 1	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Durable Objective Response Rate (ORR)

End point title	Phase 1b of Sub-Study A: Durable Objective Response Rate (ORR)[10]

End point description:

Durable ORR was defined as percentage of participants with confirmed CR/ PR according to RECIST v1.1 based on investigator assessment, lasting for at least 10 months from date of first CR/ PR until date of first documentation of PD, death/ start of new anticancer therapy. CR was defined as complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 milli meter [mm]). PR was defined as greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. PD was defined as 20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in sum is observed during therapy) with minimum absolute increase of 5 mm. Non-CR/Non-PD: Persistence of any non-target lesions and/or tumor marker level (if being followed) above normal limits. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy (approximately 38.66 months)

Notes:

[10] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Percentage of Participants				
number (confidence interval 95%)	25.0 (0.6 to 80.6)	44.4 (13.7 to 78.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Objective Response Rate

End point title	Phase 1b of Sub-Study A: Objective Response Rate[11]

End point description:

Objective response rate is defined as percentage of participants with confirmed best overall response of CR or PR according to RECIST v1.1 from the date of first dose of study treatment until the date of the first documentation of PD. CR was defined as complete disappearance of all target lesions with the exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR was defined as greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. PD was defined as 20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in the sum is observed during therapy) with a minimum absolute increase of 5 mm. Non-CR/Non-PD: Persistence of any non-target lesions and/or tumor marker level (if being followed) above the normal limits. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy (approximately 38.66 months)

Notes:

[11] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Percentage of Participants				
number (confidence interval 95%)	50.0 (6.8 to 93.2)	44.4 (13.7 to 78.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Maximum Observed Plasma Concentration (Cmax) of Sasanlimab

End point title	Phase 1b of Sub-Study A: Maximum Observed Plasma Concentration (Cmax) of Sasanlimab[12]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of

study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). "99999"= Geometric Coefficient of Variation could not be calculated as a single participant was analyzed. Here, "n" signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1 (pre-dose on Day 1, 168 hours [Day 8], 336 hours [Day 15] and Day 28 post-dose) and Cycle 5 (pre-dose on Day 1 and 168 hours [Day 8] post dose) (1 cycle= 28 days)

Notes:

[12] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Micrograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=4,9)	29.49 (± 55)	45.04 (± 38)		
Cycle 5 (n=1,1)	64.60 (± 99999)	70.90 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Area Under the Concentration Versus Time Curve Over the Dosing Interval (AUCtau) After Single Dose of Sasanlimab

End point title	Phase 1b of Sub-Study A: Area Under the Concentration Versus Time Curve Over the Dosing Interval (AUCtau) After Single Dose of Sasanlimab[13]

End point description:

AUCtau was defined as area under the plasma concentration time curve from time zero to the next dose. Pharmacokinetic (PK) parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). Here, "Subject Analyzed" (N) signifies participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Cycle 1 (pre-dose on Day 1, 168 hours [Day 8] and 336 hours [Day 15] and Day 28 post-dose) (1 cycle= 28 days)

Notes:

[13] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	7		
Units: Micrograms*hour per millilitre				
geometric mean (geometric coefficient of variation)	12500 (± 65)	24850 (± 17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Pre-dose Concentration During Multiple Dosing (Ctrough) of Sasanlimab

End point title	Phase 1b of Sub-Study A: Pre-dose Concentration During Multiple Dosing (Ctrough) of Sasanlimab[14]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. Here, Subject Analyzed signifies participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Cycle 5 Day 1 (pre-dose) (1 cycle= 28 days)

Notes:

[14] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	2		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)	37.97 (± 20)	40.24 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Time for Cmax (Tmax) of Sasanlimab

End point title	Phase 1b of Sub-Study A: Time for Cmax (Tmax) of Sasanlimab[15]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). "99999"= Median and full range could not be calculated as only 1 participant was analyzed. Here, "n" signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1 (pre-dose on Day 1, 168 hours [Day 8], 336 hours [Day 15] and Day 28 post-dose) and Cycle 5 (pre-dose on Day 1 and 168 hours [Day 8] post dose) (1 cycle= 28 days)

Notes:

[15] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Hours				
median (full range (min-max))				
Cycle 1 (n=4,9)	164 (144 to 168)	209 (143 to 359)		
Cycle 5 (n=1,1)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Ctrough of Encorafenib

End point title	Phase 1b of Sub-Study A: Ctrough of Encorafenib[16]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "n" signifies participants evaluable at specified timepoints. "99999"= data could not be calculated as values were below lower limit of quantification. "88888" = samples were not analyzed for Cycle 2 Day 1 as it was collected incorrectly due to time deviation for visits. "77777"= Geometric coefficient of variation could not be calculated for single participant

End point type	Secondary

End point timeframe:

Day 1 (pre-dose) of Cycle 1, 2 and 5; Day 15 of Cycle 1 (1 cycle= 28 days)

Notes:

[16] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=4,9)	99999 (± 99999)	99999 (± 99999)		
Cycle 1 Day 15 (n=2,4)	12.2 (± 176)	18.5 (± 50)		
Cycle 2 Day 1 (n=0,4)	88888 (± 88888)	11.1 (± 204)		
Cycle 5 Day 1 (n=1,2)	5.0 (± 77777)	7.8 (± 191)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Number of Participants With Positive Anti-Drug Antibody (ADA) and Neutralizing Antibody (NAb) Against Sasanlimab

End point title	Phase 1b of Sub-Study A: Number of Participants With Positive Anti-Drug Antibody (ADA) and Neutralizing Antibody (NAb) Against Sasanlimab[17]

End point description:

In this endpoint, number of ADA-positive and NAb-positive participants has been presented. A participant was considered ADA (or NAb) positive if (1) baseline titer was missing or negative and participant had >= 1 post-treatment positive titer (treatment-induced), or (2) positive titer at baseline and had a >= [4-fold dilution increase] in titer (equivalent to 0.602 unit increase in logarithm to base 10 (log10) titer from baseline in >= 1 post-treatment sample (treatment-boosted). Immunogenicity analysis set was a subset of the safety analysis set (participants who received at least 1 dose of study drug) and included participants who had at least 1 analyzed sasanlimab ADA/NAb sample. All participants included in 'Subjects Analyzed' contributed data to the table; however, may not have evaluable data for every row. Here, 'n' signifies participants evaluated for ADA and NAb respectively.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 until end of treatment (up to approximately 255 days) (1 cycle= 28 days)

Notes:

[17] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	9		
Units: Participants				
ADA (n=4,7)	0	1		
NAb (n=4,6)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study A: Ctrough of Binimetinib

End point title	Phase 1b of Sub-Study A: Ctrough of Binimetinib[18]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. Here, Subject Analyzed signifies participants evaluable for this endpoint. "99999"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "88888" = Geometric coefficient of variation could not be calculated for single participant. "n" signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Day 1 (pre-dose) of Cycles 1, 2, and 5 (1 cycle= 28 days)

Notes:

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

End point values	Phase 1b of SSA: Sasa(300mg)+ Enco(300mg)+ Bini (45mg)	Phase 1b of SSA: Sasa(300mg)+ Enco(450mg)+ Bini (45mg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	4		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0)	99999 (± 99999)	99999 (± 99999)		
Cycle 2 Day 1 (n=1,4)	19.2 (± 88888)	40.9 (± 98)		
Cycle 5 Day 1 (n=0,3)	99999 (± 99999)	35.7 (± 67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Number of Participants With Adverse Events Graded According to NCI-CTCAE Version 5.0

End point title	Phase 1b of Sub-Study B: Number of Participants With Adverse Events Graded According to NCI-CTCAE Version 5.0[19]

End point description:

An AE is any untoward medical occurrence in a participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs were graded by the investigator according to NCI CTCAE version 5.0; where Grade 1=mild, Grade 2=moderate, Grade 3=severe, Grade 4=life-threatening and Grade 5=death. Safety analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[19] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Participants				
Grade 1	0	0		
Grade 2	1	0		
Grade 3	2	4		
Grade 4	0	1		
Grade 5	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Number of Participants With Adverse Events Graded According to NCI-CTCAE Version 5.0

End point title	Phase 2 of Sub-Study B: Number of Participants With Adverse Events Graded According to NCI-CTCAE Version 5.0[20]

End point description:

An AE is any untoward medical occurrence in a participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs were graded by the investigator according to NCI CTCAE version 5.0; where Grade 1=mild, Grade 2=moderate, Grade 3=severe, Grade 4=life-threatening and Grade 5=death. Safety analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[20] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Participants				
Grade 1	0	0	1	
Grade 2	0	0	2	
Grade 3	2	2	2	
Grade 4	1	0	2	
Grade 5	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Number of Participants With Shift from Baseline in Hematology Parameters Values Based on CTCAE V5.0

End point title	Phase 1b of Sub-Study B: Number of Participants With Shift from Baseline in Hematology Parameters Values Based on CTCAE V5.0[21]

End point description:

Hematology parameters included: anemia, hemoglobin increased, leukocytosis, lymphocyte count decreased, lymphocyte count increased, neutrophil count decreased, platelet count decreased, white blood cell decreased. Laboratory abnormalities were graded as per NCI- CTCAE v 5.0 where, grade(G) 0= non-missing lab value that does not meet either of G1 through 4 criteria, G1=mild, G2=moderate, G3=severe and G4= life-threatening or disabling. Baseline is defined as the last assessment prior to the date/time of the first dose of study treatment. Number of participants with shift from baseline in hematology parameters by grades (as per CTCAE version 5.0) with non-zero values were reported. Safety analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[21] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Participants				
Anemia (Grade 0 to 0)	0	2		
Anemia (Grade 0 to 1)	1	0		
Anemia (Grade 1 to 1)	2	3		
Anemia (Grade 2 to 2)	0	1		

Hemoglobin increased (Grade 0 to 0)	3	6		
Leukocytosis (Grade 0 to 0)	3	6		
Lymphocyte count decreased (Grade 0 to 0)	1	1		
Lymphocyte count decreased (Grade 0 to 2)	0	1		
Lymphocyte count decreased (Grade 0 to 3)	0	1		
Lymphocyte count decreased (Grade 0 to 4)	0	1		
Lymphocyte count decreased (Grade 1 to 2)	2	0		
Lymphocyte count decreased (Grade 1 to 4)	0	1		
Lymphocyte count decreased (Grade 2 to 2)	0	1		
Lymphocyte count increased (Grade 0 to 0)	3	6		
Neutrophil count decreased (Grade 0 to 0)	3	6		
Platelet count decreased (Grade 0 to 0)	2	5		
Platelet count decreased (Grade 0 to 1)	1	1		
White blood cell decreased (Grade 0 to 0)	3	5		
White blood cell decreased (Grade 0 to 1)	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Number of Participants With Shift from Baseline in Chemistry Parameters Values Based on CTCAE V5.0

End point title	Phase 1b of Sub-Study B: Number of Participants With Shift from Baseline in Chemistry Parameters Values Based on CTCAE V5.0[22]

End point description:

Chemistry parameters included: alanine aminotransferase (ALT) increased, alkaline phosphatase (ALP) increased, aspartate aminotransferase (AST) increased, blood bilirubin increased, creatinine phosphokinase (CPK) increased, chronic kidney disease (CKD), creatinine increased, hypercalcemia, hyperkalemia, hypermagnesemia, hypernatremia, hypoalbuminemia, hypocalcemia, hypoglycemia, hypokalemia, hypomagnesemia, hyponatremia, lipase increased, serum amylase increased. Chemistry abnormalities were graded as per NCI- CTCAE v 5.0 where, grade(G) 0= non-missing lab value that does not meet either of G1 through 4 criteria, G1=mild, G2=moderate, G3=severe and G4= life-threatening or disabling. Baseline is defined as the last assessment prior to the date/time of the first dose of study treatment. Number of participants with shift from baseline in chemistry parameters by grades (as per CTCAE version 5.0) with non-zero values were reported. Safety analysis set used.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[22] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Participants				
ALT increased (Grade 0 to 0)	1	5		
ALT increased (Grade 0 to 1)	2	0		
ALT increased (Grade 0 to 2)	0	1		
ALP increased (Grade 0 to 0)	2	4		
ALP increased (Grade 0 to 1)	0	2		
ALP increased (Grade 1 to 2)	1	0		
AST increased (Grade 0 to 0)	0	5		
AST increased (Grade 0 to 1)	1	0		
AST increased (Grade 0 to 3)	0	1		
AST increased (Grade 1 to 0)	1	0		
AST increased (Grade 1 to 1)	1	0		
Blood bilirubin increased (Grade 0 to 0)	3	6		
CPK increased (Grade 0 to 0)	3	5		
CPK increased (Grade 1 to 0)	0	1		
Chronic kidney disease (Grade 0 to 0)	1	0		
Chronic kidney disease (Grade 0 to 1)	1	2		
Chronic kidney disease (Grade 0 to 2)	0	1		
Chronic kidney disease (Grade 1 to 2)	0	1		
Chronic kidney disease (Grade 2 to 2)	1	2		
Creatinine increased (Grade 0 to 0)	2	3		
Creatinine increased (Grade 1 to 1)	1	2		
Creatinine increased (Grade 1 to 2)	0	1		
Hypercalcemia (Grade 0 to 0)	1	5		
Hypercalcemia (Grade 0 to 1)	2	1		
Hyperkalemia (Grade 0 to 0)	2	5		
Hyperkalemia (Grade 0 to 1)	1	1		
Hypermagnesemia (Grade 0 to 0)	3	6		
Hypernatremia (Grade 0 to 0)	3	6		
Hypoalbuminemia (Grade 0 to 0)	2	2		
Hypoalbuminemia (Grade 0 to 1)	1	1		
Hypoalbuminemia (Grade 0 to 2)	0	1		
Hypoalbuminemia (Grade 1 to 2)	0	1		
Hypoalbuminemia (Grade 2 to 2)	0	1		
Hypocalcemia (Grade 0 to 0)	3	6		
Hypoglycemia (Grade 0 to 0)	2	5		
Hypoglycemia (Grade 0 to 1)	1	1		
Hypokalemia (Grade 0 to 0)	2	4		
Hypokalemia (Grade 0 to 2)	1	2		
Hypomagnesemia (Grade 0 to 0)	1	5		
Hypomagnesemia (Grade 0 to 1)	1	1		
Hypomagnesemia (Grade 2 to 1)	0	1		
Hyponatremia (Grade 0 to 0)	2	4		
Hyponatremia (Grade 0 to 1)	1	2		
Lipase increased (Grade 0 to 0)	3	4		
Lipase increased (Grade 0 to 1)	0	2		

Serum amylase increased (Grade 0 to 0)	3	4		
Serum amylase increased (Grade 0 to 1)	0	1		
Serum amylase increased (Grade 1 to 2)	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Number of Participants With Shift From Baseline in Hematology Parameter Values Based on CTCAE V5.0

End point title	Phase 2 of Sub-Study B: Number of Participants With Shift From Baseline in Hematology Parameter Values Based on CTCAE V5.0[23]

End point description:

Hematology parameters included: anemia, hemoglobin increased, lymphocyte count decreased and increased, leukocytosis, neutrophil count decreased, platelet count decreased, white blood cell decreased. Number of participants with shift from baseline in hematology parameters by grades as per CTCAE version 5.0 with non-zero values were reported. Grade 0= non-missing lab value that does not meet either of Grade 1 through 4 criteria; Grade 1= mild; Grade 2= moderate; Grade 3= severe and Grade 4= life-threatening or disabling. Safety analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[23] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Participants				
Anemia (Grade 0 to 0)	1	0	5	
Anemia (Grade 0 to 1)	1	0	0	
Anemia (Grade 1 to 0)	0	0	1	
Anemia (Grade 1 to 1)	0	2	1	
Anemia (Grade 2 to 2)	1	0	0	
Hemoglobin increased (Grade 0 to 0)	3	2	6	
Hemoglobin increased (Grade 0 to 1)	0	0	1	
Leukocytosis (Grade 0 to 0)	3	2	7	
Lymphocyte count decreased (Grade 0 to 0)	0	0	3	
Lymphocyte count decreased (Grade 0 to 2)	0	0	2	

Lymphocyte count decreased (Grade 0 to 3)	1	1	0	
Lymphocyte count decreased (Grade 1 to 2)	0	1	0	
Lymphocyte count decreased (Grade 1 to 3)	1	0	1	
Lymphocyte count decreased (Grade 2 to 4)	1	0	0	
Lymphocyte count decreased (Grade 3 to 4)	0	0	1	
Lymphocyte count increased (Grade 0 to 0)	3	2	7	
Neutrophil count decrease (Grade 0 to 0)	2	2	7	
Neutrophil count decrease (Grade 0 to 2)	1	0	0	
Platelet count decreased (Grade 0 to 0)	2	2	6	
Platelet count decreased (Grade 0 to 2)	1	0	1	
White blood Cell decreased (Grade 0 to 0)	1	1	5	
White blood Cell decreased (Grade 0 to 1)	1	0	2	
White blood Cell decreased (Grade 0 to 3)	1	0	0	
White blood Cell decreased (Grade 1 to 1)	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Number of Participants With Shift From Baseline in Chemistry Parameter Values Based on CTCAE V5.0

End point title	Phase 2 of Sub-Study B: Number of Participants With Shift From Baseline in Chemistry Parameter Values Based on CTCAE V5.0[24]

End point description:

Chemistry parameters included: ALT increased, ALP increased, AST increased, blood bilirubin increased, chronic kidney disease, CPK increased, creatinine increased, hypercalcemia, hyperkalemia, hypermagnesemia, hypernatremia, hypoalbuminemia, hypocalcemia, hypoglycemia, hypokalemia, hypomagnesemia, hyponatremia, lipase increased, serum amylase increased. Number of participants with maximum CTCAE V5.0 grade in chemistry parameters with non-zero values were reported. Grade 0= non-missing lab value that does not meet either of Grade 1 through 4 criteria; Grade 1= mild; Grade 2= moderate; Grade 3= severe and Grade 4= life-threatening or disabling. Safety analysis set included all participants who received at least 1 dose of study drug. Here, "n" signifies number of participants evaluable for the specified rows.

End point type	Secondary

End point timeframe:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 39.3 months; maximum follow-up approximately 39.66 months)

Notes:

[24] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Participants				
ALT increased: Grade 0 to 0 (n=3,2,7)	1	1	3	
ALT increased: Grade 0 to 1 (n=3,2,7)	1	0	3	
ALT increased: Grade 0 to 3 (n=3,2,7)	1	1	0	
ALT increased: Grade 0 to 4 (n=3,2,7)	0	0	1	
ALP increased: Grade 0 to 0 (n=3,2,7)	0	1	3	
ALP increased: Grade 0 to 1 (n=3,2,7)	2	1	2	
ALP increased: Grade 1 to 0 (n=3,2,7)	1	0	2	
AST increased: Grade 0 to 0 (n=3,2,7)	1	1	2	
AST increased: Grade 0 to 1 (n=3,2,7)	1	0	4	
AST increased: Grade 0 to 3 (n=3,2,7)	1	1	0	
AST increased: Grade 0 to 4 (n=3,2,7)	0	0	1	
Blood bilirubin increased: Grade 0 to 0 (n=3,2,7)	2	1	6	
Blood bilirubin increased: Grade 0 to 1 (n=3,2,7)	1	1	0	
Blood bilirubin increased: Grade 0 to 3 (n=3,2,7)	0	0	1	
CPK increased: Grade 0 to 0 (n=3,2,6)	3	2	5	
CPK increased: Grade 1 to 0 (n=3,2,6)	0	0	1	
Chronic kidney disease: Grade 0 to 0 (n=3,2,7)	1	2	5	
Chronic kidney disease: Grade 0 to 2 (n=3,2,7)	0	0	1	
Chronic kidney disease: Grade 0 to 3 (n=3,2,7)	1	0	0	
Chronic kidney disease: Grade 1 to 2 (n=3,2,7)	1	0	0	
Chronic kidney disease: Grade 2 to 2 (n=3,2,7)	0	0	1	
Creatinine increased: Grade 0 to 0 (n=3,2,7)	1	2	5	
Creatinine increased: Grade 0 to 1 (n=3,2,7)	0	0	1	
Creatinine increased: Grade 0 to 3 (n=3,2,7)	1	0	0	
Creatinine increased: Grade 1 to 1 (n=3,2,7)	1	0	1	
Hypercalcemia: Grade 0 to 0 (n=3,2,7)	2	2	7	
Hypercalcemia: Grade 0 to 1 (n=3,2,7)	1	0	0	
Hyperkalemia: Grade 0 to 0 (n=3,2,7)	2	1	6	
Hyperkalemia: Grade 0 to 1 (n=3,2,7)	0	1	1	
Hyperkalemia: Grade 0 to 2(n=3,2,7)	1	0	0	
Hypermagnesemia: Grade 0 to 0 (n=3,2,7)	3	2	6	
Hypermagnesemia: Grade 0 to 1 (n=3,2,7)	0	0	1	
Hypernatremia: Grade 0 to 0 (n=3,2,7)	3	2	6	
Hypernatremia: Grade 0 to 1 (n=3,2,7)	0	0	1	

Hypoalbuminemia: Grade 0 to 0 (n=3,2,7)	1	2	4	
Hypoalbuminemia: Grade 0 to 1 (n=3,2,7)	1	0	1	
Hypoalbuminemia: Grade 0 to 2 (n=3,2,7)	1	0	2	
Hypocalcemia: Grade 0 to 0 (n=3,2,7)	2	2	6	
Hypocalcemia: Grade 0 to 1 (n=3,2,7)	1	0	0	
Hypocalcemia: Grade 1 to 1 (n=3,2,7)	0	0	1	
Hypoglycemia: Grade 0 to 0 (n=3,2,7)	3	2	7	
Hypokalemia: Grade 0 to 0 (n=3,2,7)	2	1	4	
Hypokalemia: Grade 0 to 2 (n=3,2,7)	0	1	2	
Hypokalemia: Grade 0 to 3 (n=3,2,7)	1	0	0	
Hypokalemia: Grade 2 to 2 (n=3,2,7)	0	0	1	
Hypomagnesemia: Grade 0 to 0 (n=3,2,7)	2	2	3	
Hypomagnesemia: Grade 0 to 1 (n=3,2,7)	0	0	4	
Hypomagnesemia: Grade 0 to 2 (n=3,2,7)	1	0	0	
Hyponatremia: Grade 0 to 0 (n=3,2,7)	2	1	4	
Hyponatremia: Grade 0 to 1 (n=3,2,7)	1	0	0	
Hyponatremia: Grade 0 to 3 (n=3,2,7)	0	0	3	
Hyponatremia: Grade 1 to 3 (n=3,2,7)	0	1	0	
Lipase increased: Grade 0 to 0 (n=3,2,7)	1	2	5	
Lipase increased: Grade 0 to 1 (n=3,2,7)	2	0	0	
Lipase increased: Grade 0 to 2 (n=3,2,7)	0	0	1	
Lipase increased: Grade 0 to 3 (n=3,2,7)	0	0	1	
Serum amylase increased: Grade 0 to 0 (n=3,2,7)	2	2	4	
Serum amylase increased: Grade 0 to 1 (n=3,2,7)	1	0	1	
Serum amylase increased: Grade 2 to 2 (n=3,2,7)	0	0	1	
Serum amylase increased: Grade 2 to 3 (n=3,2,7)	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Duration of Response (DR)

End point title	Phase 1b of Sub-Study B: Duration of Response (DR)[25]

End point description:

DR was defined for participants with confirmed objective response (OR) as time from date of first documentation of OR to the date of first documentation of PD or death (any cause), whichever occurred first. OR=CR or PR according to RECIST v1.1 based on investigator assessment. CR and PR must be confirmed by repeat assessments performed no <4 weeks after criteria for response were first met. CR=complete disappearance of all target lesions (TLs) with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR=greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions (TMLs). PD=20% increase in sum of diameters of TMLs above smallest sum observed (over baseline if no decrease in sum was observed

during therapy), with a minimum absolute increase of 5 mm.

End point type	Secondary

End point timeframe:

From the date of first documentation of OR to the date of first documentation of PD or death, whichever occurred first (maximum of 21 months)

Notes:

[25] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[26]	0[27]		
Units: Months				
number (confidence interval 95%)	(to)	(to)		

Notes:

[26] - Data not estimable due to insufficient number of participants(with events) evaluable for endpoint.

[27] - Data not estimable due to insufficient number of participants(with events) evaluable for endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Objective Response Rate

End point title	Phase 1b of Sub-Study B: Objective Response Rate[28]

End point description:

ORR was defined as percentage of participants with confirmed CR or PR according to RECIST v1.1 based on investigator assessment, from the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy. CR was defined as complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR was defined as greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. PD was defined as 20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in the sum was observed during therapy), with a minimum absolute increase of 5 mm. Two sided 95% CI was based on Clopper-Pearson method. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy, whichever occurred first (maximum of 21 months)

Notes:

[28] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Percentage of participants				

number (confidence interval 95%)	0.0 (0.0 to 70.8)	0.0 (0.0 to 45.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Time to Tumor Response (TTR)

End point title	Phase 2 of Sub-Study B: Time to Tumor Response (TTR)[29]

End point description:

TTR is defined for participants with confirmed OR as the time from the date of first dose of study treatment to the date of first documentation of objective response (CR or PR) which was subsequently confirmed. CR=complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR=greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. Full analysis set included all participants who received at least 1 dose of study drug. "99999"= Median and full range could not be calculated as sonly 1 participant was analyzed. Here, Subjects Analyzed signifies participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From the date of first dose of study treatment to the date of first documentation of objective response (CR or PR) (maximum of 21 months)

Notes:

[29] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0[30]	1	
Units: Months				
median (full range (min-max))	99999 (-99999 to 99999)	(to)	99999 (-99999 to 99999)	

Notes:

[30] - Data not estimable due to insufficient number of participants(with events) evaluable for endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Progression-Free Survival (PFS)

End point title	Phase 1b of Sub-Study B: Progression-Free Survival (PFS)[31]

End point description:

PFS is defined as the time from the date of first dose of study treatment to the date of first documentation of PD or death due to any cause, whichever occurred first. PD=20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in

sum was observed during therapy), with a minimum absolute increase of 5 mm. Full analysis set included all participants who received at least 1 dose of study drug. "99999"= Data could not be calculated due to insufficient number of participants with event. Here, Subjects Analyzed signifies participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From the date of first dose of study treatment to the date of first documentation of PD or death due to any cause, whichever occurred first (maximum of 21 months)

Notes:

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

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	5		
Units: Months				
median (confidence interval 95%)	3.6 (0.7 to 99999)	6.5 (3.6 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Time to Tumor Response (TTR)

End point title	Phase 1b of Sub-Study B: Time to Tumor Response (TTR)[32]

End point description:

TTR is defined for participants with confirmed objective response as the time from the date of first dose of study treatment to the date of first documentation of objective response (CR or PR) which was subsequently confirmed. CR=complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR=greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions.

End point type	Secondary

End point timeframe:

From the date of first dose of study treatment to the date of first documentation of objective response (CR or PR) (maximum of 21 months)

Notes:

[32] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[33]	0[34]		
Units: Months				
median (confidence interval 95%)	(to)	(to)		

Notes:

[33] - Data not estimable due to insufficient number of participants(with events) evaluable for endpoint.

[34] - Data not estimable due to insufficient number of participants(with events) evaluable for endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Duration of Response (DR)

End point title	Phase 2 of Sub-Study B: Duration of Response (DR)[35]

End point description:

DR: participants with confirmed OR as time from date of first documentation of OR to date of first documentation of PD/death (any cause), whichever occurred first. OR=CR/PR per RECIST v1.1 based on investigator assessment. CR and PR must be confirmed by repeat assessments performed no <4 weeks after criteria for response were first met. CR=complete disappearance of all TLs with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 mm). PR=greater >= 30% decrease under baseline of sum of diameters of all TMLs. PD=20% increase in sum of diameters of TMLs above smallest sum observed, with minimum absolute increase of 5 mm. 99999= Median, 95% CI could not be calculated as only participant analyzed did not have an event of interest. 88888= 95% CI could not be calculated as 1 participant was analyzed, who experienced an event of interest. Full analysis set. N= participants evaluable for this endpoint and included only those participants with confirmed OR.

End point type	Secondary

End point timeframe:

From date of first documentation of OR to the date of first documentation of PD or death, whichever occurred first (maximum of 21 months)

Notes:

[35] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0[36]	1	
Units: Months				
median (confidence interval 95%)	99999 (-99999 to 99999)	(to)	5.8 (-88888 to 88888)	

Notes:

[36] - No participant had confirmed OR

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Progression-Free Survival (PFS)

End point title	Phase 2 of Sub-Study B: Progression-Free Survival (PFS)[37]

End point description:

PFS is defined as the time from the date of first dose of study treatment to the date of first

documentation of PD or death due to any cause, whichever occurred first. PD=20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in sum was observed during therapy), with a minimum absolute increase of 5 mm. "99999" = Data could not be calculated due to insufficient participants with event. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first dose of study treatment to the date of first documentation of PD or death due to any cause, whichever occurred first (maximum of 21 months)

Notes:

[37] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Months				
median (confidence interval 95%)	4.2 (4.0 to 99999)	99999 (-99999 to 99999)	4.0 (1.4 to 4.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Overall Survival (OS)

End point title	Phase 2 of Sub-Study B: Overall Survival (OS)[38]

End point description:

OS is defined as the time from the date of first dose of study treatment to the date of death due to any cause. Participants last known to be alive were planned to be censored at the date of last contact. "99999" = Data could not be calculated due to insufficient participants with event. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first dose of study treatment to the date of first documentation of PD or death due to any cause, whichever occurred first (maximum of 21 months)

Notes:

[38] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Months				
median (confidence interval 95%)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	4.0 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Cmax of Sasanlimab

End point title	Phase 1b of Sub-Study B: Cmax of Sasanlimab[39]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose, 168 hours post-dose on Day 1, Cycle 5: pre-dose, 168 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

[39] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	3		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=3,3)	8840 (± 127)	11570 (± 79)		
Cycle 5 (n=2,3)	23080 (± 99999)	47340 (± 42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Cmax of SEA-TGT

End point title	Phase 1b of Sub-Study B: Cmax of SEA-TGT[40]

End point description:

PK parameter analysis set: subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. Subjects Analyzed signifies participants evaluable for this endpoint. n= participants evaluable at specified timepoints. Data for only those participants who received SEA-TGT were planned to be reported for this outcome measure.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose, 168 hours post-dose on Day 1, Cycle 5: pre-dose, 168 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

[40] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)			
Subject group type	Reporting group			
Number of subjects analysed	5			
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=5)	42550 (± 109)			
Cycle 5 (n=4)	32660 (± 17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Cmax of Axitinib

End point title	Phase 1b of Sub-Study B: Cmax of Axitinib[41]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug (i.e., sasanlimab). "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose on Day 1, Day 8 and 3 hours post-dose on Day 1; Cycle 5: pre-dose on Day 1, Day 8 and 3 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

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

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	5		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=2, 5)	5.094 (± 99999)	22.81 (± 80)		
Cycle 1 Day 8 (n=1,3)	3.440 (± 77777)	13.74 (± 106)		
Cycle 5 Day 1 (n=0,4)	88888 (± 88888)	33.79 (± 73)		
Cycle 5 Day 8 (n=1,2)	13.10 (± 77777)	24.85 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Cmax of sasanlimab

End point title	Phase 2 of Sub-Study B: Cmax of sasanlimab[42]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose, 168 hours post-dose on Day 1, Cycle 5: pre-dose, 168 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

[42] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=3,2,7)	11780 (± 45)	13810 (± 99999)	10350 (± 45)	
Cycle 5 (n=0,1,1)	88888 (± 88888)	43500 (± 77777)	20600 (± 77777)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Cmax of axitinib

End point title	Phase 2 of Sub-Study B: Cmax of axitinib[43]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose on Day 1, Day 8 and 3 hours post-dose on Day 1; Cycle 5: pre-dose on Day 1, Day 8 and 3 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

[43] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LN SCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	6	
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=3,2,6)	37.43 (± 85)	18.23 (± 99999)	11.18 (± 112)	

Cycle 1 Day 8 (n=1,1,4)	39.50 (± 77777)	2.360 (± 77777)	2.708 (± 132)	
Cycle 5 Day 1 (n=0,1,1)	88888 (± 88888)	11.10 (± 77777)	7.710 (± 77777)	
Cycle 5 Day 8 (n=0,0,0)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Cmax of SEA-TGT

End point title	Phase 2 of Sub-Study B: Cmax of SEA-TGT[44]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose, 168 hours post-dose on Day 1, Cycle 5: pre-dose, 168 hours post-dose on Day 1 (1 cycle= 21 days)

Notes:

[44] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=3,2,7)	36970 (± 36)	35500 (± 99999)	30590 (± 39)	
Cycle 5 (n=0,1,1)	88888 (± 88888)	43000 (± 77777)	44900 (± 77777)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing

(Ctrough) of Sasanlimab

End point title	Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Sasanlimab[45]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 and Cycle 5 Day 1 (1 cycle= 21 days)

Notes:

[45] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2	4		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=0,0)	88888 (± 88888)	88888 (± 88888)		
Cycle 5 (n=2,4)	23000 (± 99999)	23170 (± 29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Axitinib

End point title	Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Axitinib[46]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 and Day 8; pre-dose on Cycle 5 Day 1 and Day 8 (1 cycle= 21 days)

Notes:

[46] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0)	88888 (± 88888)	88888 (± 88888)		
Cycle 1 Day 8 (n=1,3)	3.440 (± 77777)	13.74 (± 106)		
Cycle 5 Day 1 (n=0,2)	88888 (± 88888)	29.42 (± 99999)		
Cycle 5 Day 8 (n=1,2)	13.10 (± 77777)	24.85 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of SEA-TGT

End point title	Phase 1b of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of SEA-TGT[47]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. Data for only those participants who received SEA-TGT were planned to be reported hence Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg) arm was not reported. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. Here, Subjects Analyzed signifies participants evaluable for this endpoint and ‘n’ signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1; pre-dose on Cycle 5 Day 1 (1 cycle= 21 days)

Notes:

[47] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=0)	88888 (± 88888)			
Cycle 5 (n=4)	4813 (± 35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Sasanlimab

End point title	Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Sasanlimab[48]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints. This endpoint was not applicable for participants of ''Phase 2 of SSB: 1L NSCLC / PD-L1: TPS 1-49%''

End point type	Secondary

End point timeframe:

Cycle 1: pre-dose on Day 1, Cycle 5: pre-dose on Day 1 (1 cycle= 21 days)

Notes:

[48] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	2		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=0,2)	88888 (± 88888)	87.01 (± 99999)		
Cycle 5 (n=1,1)	30400 (± 77777)	20000 (± 77777)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Axitinib

End point title	Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of Axitinib[49]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "88888"= Geometric mean and geometric coefficient of variation could not be calculated as zero participants were analyzed. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 and Day 8; pre-dose on Cycle 5 Day 1 and Day 8 (1 cycle= 21 days)

Notes:

[49] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1[50]	1	4	
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=0,0,0)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	
Cycle 1 Day 8 (n=1,1,4)	39.50 (± 77777)	2.360 (± 77777)	2.708 (± 132)	
Cycle 5 Day 1 (n=0,0,1)	88888 (± 88888)	88888 (± 88888)	3.630 (± 77777)	
Cycle 5 Day 8 (n=0,0,0)	88888 (± 88888)	88888 (± 88888)	88888 (± 88888)	

Notes:

[50] - This endpoint was not applicable for participants of ''Phase 2 of SSB: 1L NSCLC / PD-L1: TPS 1-49%''

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1b of Sub-Study B: Number of Participants With Positive Anti-Drug Antibody (ADA) Against Sasanlimab and SEA-TGT

End point title	Phase 1b of Sub-Study B: Number of Participants With Positive Anti-Drug Antibody (ADA) Against Sasanlimab and SEA-TGT[51]

End point description:

A participant was considered ADA (or NAb) positive if (1) baseline titer was missing or negative and participant had >= 1 post-treatment positive titer (treatment-induced), or (2) positive titer at baseline and had a >= [4-fold dilution increase] in titer (equivalent to 0.602 unit increase in logarithm to base 10 (log10) titer from baseline in >= 1 post-treatment sample (treatment-boosted). Immunogenicity analysis set included participants who had at least 1 analyzed sasanlimab ADA/NAb sample. Here ''n'' signifies number of participants with at least one post-treatment ADA result for respective category.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 until end of treatment (up to approximately 21 months) (1 cycle= 21 days)

Notes:

[51] - 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 end point is reporting statistics for the arms specified

End point values	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Participants				
ADA against sasanlimab (n=3,6)	0	1		
ADA against sasanlimab (n=0,6)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of SEA-TGT

End point title	Phase 2 of Sub-Study B: Pre-dose Concentration During Multiple Dosing (Ctrough) of SEA-TGT[52]

End point description:

PK parameter analysis set was subset of safety analysis set (participants who received at least 1 dose of study drug) with participants who had at least 1 of PK parameters of interest for measured analytes related to study drug. "99999"= Geometric coefficient of variation could not be calculated as at least 3 values were required and this criterion could not be fulfilled due to lack of available data. "77777" = Geometric coefficient of variation could not be calculated for single participant. Here, Subjects Analyzed signifies participants evaluable for this endpoint and 'n' signifies participants evaluable at specified timepoints. This endpoint was not applicable for participants of ''Phase 2 of SSB: 1L NSCLC / PD-L1: TPS 1-49%''

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1; pre-dose on Cycle 5 Day 1 (1 cycle= 21 days)

Notes:

[52] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	2		
Units: Nanograms per millilitre				
geometric mean (geometric coefficient of variation)				
Cycle 1 (n=1,2)	55.00 (± 77777)	24.47 (± 99999)		
Cycle 1 (n=1,1)	5770 (± 77777)	8490 (± 132)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Number of Participants With Positive Anti-Drug Antibody (ADA) Against Sasanlimab and SEA-TGT

End point title	Phase 2 of Sub-Study B: Number of Participants With Positive Anti-Drug Antibody (ADA) Against Sasanlimab and SEA-TGT[53]

End point description:

Immunogenicity analysis set included participants who had at least 1 analyzed sasanlimab ADA/NAb sample.

End point type	Secondary

End point timeframe:

Pre-dose on Cycle 1 Day 1 until end of treatment (up to approximately 21 months) (1 cycle= 21 days)

Notes:

[53] - 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 end point is reporting statistics for the arms specified

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Participants				
ADA against sasanlimab	0	0	0	
ADA against SEA-TGT	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2 of Sub-Study B: Objective Response Rate by PD-L1 Expression in Available Tumor Tissue

End point title	Phase 2 of Sub-Study B: Objective Response Rate by PD-L1 Expression in Available Tumor Tissue[54]

End point description:

ORR was defined as percentage of participants with confirmed CR or PR according to RECIST v1.1 based on investigator assessment, from the date of first CR or PR until the date of the first documentation of disease progression (PD), death, or start of new anticancer therapy. CR was defined as complete disappearance of all target lesions with exception of nodal disease. All target nodes must decrease to normal size (short axis <10 millimeter [mm]). PR was defined as greater than or equal to 30% decrease under baseline of the sum of diameters of all target measurable lesions. PD was defined as 20% increase in sum of diameters of target measurable lesions above smallest sum observed (over baseline if no decrease in the sum was observed during therapy), with a minimum absolute increase of 5 mm. Full analysis set included all participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

From the date of first CR or PR until the date of the first documentation of PD, death, or start of new anticancer therapy (maximum of 21 months)

Notes:

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

End point values	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	2	7	
Units: Percentage of participants				
number (confidence interval 95%)				
ADA against sasanlimab	33.3 (0.8 to 90.6)	0.0 (0.0 to 84.2)	14.3 (0.4 to 57.9)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From the start of study treatment (Cycle1 Day1) up to 30 days after last dose of study treatment (maximum exposure = 38.66 months; maximum follow-up approximately 39.66 months)

Adverse event reporting additional description:

Same event may appear as both non-serious adverse event (non-SAE) and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE. Safety analysis set included all participants who received at least 1 dose of study drug.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v27.1

Reporting groups

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini (45mg)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) with BRAFV600 mutations were administered a single dose of sasanlimab 300 milligrams (mg) subcutaneously on Day 1 of each cycle along with once daily (QD) oral dose of 300 mg encorafenib and twice daily (BID) oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg every 3 weeks (Q3W) subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC who received 1 or 2 lines of therapy for advanced/metastatic NSCLC and whose disease has progressed on prior PD-1/ PD-L1 therapy and who have PD-L1 TPS >= 1% were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and 1 mg/kg IV infusion Q3W SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC with who were treatment-naïve for advanced/metastatic disease with low programmed death ligand - 1 (PD-L1) levels Tumor proportion score (TPS)-49 percent (%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)

Reporting group description:

Participants with NSCLC with who were treatment-naïve for advanced/metastatic disease with high PD-L1 (TPS greater than or equal to [>=]50%) were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W IV infusion of 1 mg/kg SEA+ TGT on Day 1 of each cycle during each 21-day cycle.

Reporting group title	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini (45mg)

Reporting group description:

Participants with NSCLC with BRAFV600 mutations were administered a single dose of sasanlimab 300 mg subcutaneously on Day 1 of each cycle along with QD oral dose of 450 mg encorafenib and BID oral dose of 45 mg binimetinib during each 28-day cycle.

Reporting group title	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)

Reporting group description:

Participants with NSCLC and who received any line of therapy for advanced/metastatic NSCLC were administered a single dose of sasanlimab 225 mg Q3W subcutaneously along with BID oral dose of 5 mg axitinib on Day 1 of each cycle and Q3W intravenous (IV) infusion of 1 milligram per kilogram (mg/kg) SEA-TGT on Day 1 of each cycle during each 21-day cycle.

Serious adverse events	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini(45mg)	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	4 / 7 (57.14%)
number of deaths (all causes)	0	1	3
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 tamponade			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Rhabdomyolysis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Septic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (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
Lower respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini(45mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	7 / 9 (77.78%)
number of deaths (all causes)	1	0	4
number of deaths resulting from adverse events	0	0	2
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Ejection fraction decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Cardiac tamponade			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (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
Enteritis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (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
Ureterolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rhabdomyolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Infections and infestations			
Septic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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	0 / 3 (0.00%)	0 / 2 (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
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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

Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (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
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	1		
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ejection fraction decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac tamponade			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Headache				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Colitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Hepatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureterolithiasis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Rhabdomyolysis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Septic shock				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Phase 1b of SSA: Sasa(300mg)+Enco(300mg)+Bini(45mg)	Phase 1b of SSB: Sasanlimab (225 mg) + Axitinib (5 mg)	Ph2SSB:2/3LNSCLC/PDL1:TPS>=1%(mg)Sasa225+Axit5+SEA-TGT(1/kg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	3 / 7 (42.86%)
occurrences (all)	1	3	5
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nodule			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Vulvovaginal dryness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysmenorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	4 / 7 (57.14%)
occurrences (all)	0	0	4
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	1	3	2
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	3 / 3 (100.00%)	2 / 7 (28.57%)
occurrences (all)	1	5	2
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	1	1	3
Blood corticotrophin increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
White blood cell count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ear discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Uveitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Narrow anterior chamber angle			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular discomfort			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Retinal fovea disorder			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Macular oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	1	1	3

Constipation			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Anorectal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	3 / 7 (42.86%)
occurrences (all)	2	0	5
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Visceral venous thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Tooth discolouration			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Granuloma annulare			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pain of skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Psoriasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Rash maculo-papular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hyperkeratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Purpura			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nodular rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin tightness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Glycosuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	0	6	2
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Connective tissue disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Acne pustular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2SSB:1L NSCLC PDL1:TPS1-49%(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Ph2SSB:1L NSCLC/PDL1:TPS>=50%9(mg)Sasa225+Axit5+SEA-TGT(1/kg)	Phase 1b of SSA: Sasa(300mg)+Enco(450mg)+Bini(45mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 2 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	4	1	4
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Thrombosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Catheter site hypersensitivity			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	4 / 9 (44.44%)
occurrences (all)	3	1	5
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	5
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Vulvovaginal dryness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	3	0	3
Dysphonia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	3
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	4 / 9 (44.44%)
occurrences (all)	5	2	9
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Blood bicarbonate decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	3 / 9 (33.33%)
occurrences (all)	4	3	7
Amylase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	2
Blood creatinine increased			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Blood corticotrophin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	10	3	0
Lipase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
International normalised ratio increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	1	1	2
Haemoglobin decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	4	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	4 / 9 (44.44%)
occurrences (all)	0	0	15
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	2 / 2 (100.00%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Headache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1

Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	3	0	10
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	4
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eye disorders			

Dry eye			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Narrow anterior chamber angle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Ocular discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Retinal fovea disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Macular oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	2
Abdominal pain upper			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	4	0	5
Constipation			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
Anorectal discomfort			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	2	0	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Vomiting			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Visceral venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tooth discolouration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Alopecia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Granuloma annulare			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	4
Pain of skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 3 (66.67%)	1 / 2 (50.00%)	3 / 9 (33.33%)
occurrences (all)	2	4	6
Hyperkeratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nodular rash			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	4 / 9 (44.44%)
occurrences (all)	1	0	13
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	3 / 9 (33.33%)
occurrences (all)	0	2	4
Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	5 / 9 (55.56%)
occurrences (all)	1	0	11
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Connective tissue disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
Candida infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Rash pustular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	5
Acne pustular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	8	0	2
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	2	1	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 2 (0.00%)	2 / 9 (22.22%)
occurrences (all)	5	0	3
Hyperphosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 9 (11.11%)
occurrences (all)	1	1	6
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	2
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2

Non-serious adverse events	Phase 1b of SSB: Sasa (225mg) + Axit (5 mg) + SEA-TGT(1mg/kg)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	4		
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Embolism			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Catheter site hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fatigue			

subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	5		
Malaise			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nodule			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Vulvovaginal dryness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	3		
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood bicarbonate decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Amylase increased			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Blood creatinine increased			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	3		
Blood corticotrophin increased			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Blood creatine increased				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Blood albumin decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Troponin increased				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Platelet count decreased				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Neutrophil count decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Lymphocyte count decreased				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	7			
Lipase increased				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	3			
International normalised ratio increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Electrocardiogram T wave inversion				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
C-reactive protein increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			

Blood thyroid stimulating hormone decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Injury, poisoning and procedural complications Infusion related reaction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 2		
Cardiac disorders Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Headache subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Neuralgia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Dysgeusia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Paraesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Presyncope subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 4		
Leukocytosis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Neutropenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Ear and labyrinth disorders			

Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Uveitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Narrow anterior chamber angle			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Ocular discomfort			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Retinal fovea disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Macular oedema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

Abdominal distension				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Abdominal pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Abdominal pain upper				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	3 / 6 (50.00%)			
occurrences (all)	4			
Constipation				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	2			
Anorectal discomfort				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Mouth ulceration				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Odynophagia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Oral pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			

Pancreatitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Visceral venous thrombosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tooth discolouration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Erythema			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Granuloma annulare				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pain of skin				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	2			
Rash				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	3			
Psoriasis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Rash erythematous				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	4 / 6 (66.67%)			
occurrences (all)	4			
Hyperkeratosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Purpura				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			

Skin exfoliation subjects affected / exposed occurrences (all) Skin lesion subjects affected / exposed occurrences (all) Nodular rash subjects affected / exposed occurrences (all) Skin tightness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Renal and urinary disorders Glycosuria subjects affected / exposed occurrences (all) Proteinuria subjects affected / exposed occurrences (all) Urinary incontinence subjects affected / exposed occurrences (all) Pollakiuria subjects affected / exposed occurrences (all) Ureterolithiasis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1 3 / 6 (50.00%) 9 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all) Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Flank pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Arthralgia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Connective tissue disorder			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Candida infection			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rash pustular			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Acne pustular			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		

Hypercalcaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypoglycaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Hyponatraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypoalbuminaemia				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	6			
Hyperphosphataemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hyperkalaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	2			
Hypomagnesaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypophosphataemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	2			
Hypercholesterolaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			

Hypernatraemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 October 2021	For Sub-Study B, reduced frequency of troponin clinical laboratory testing from every visit to Screening/C1D1 and when clinically indicated, because routine monitoring of troponin is not indicated for axitinib or approved immune checkpoint inhibitors (Section 13.10.1). Injectables were removed from the list of combined hormonal birth control methods that are highly effective and user dependent per new Pfizer standard because there are no approved injectable agents in this category (Sections 12.10.2.4 and 13.10.2.4.)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to a business decision, no participant was enrolled in Phase 2 of sub-study A. Hence, Phase 2 was not initiated, and no data was collected and there are no results for this in the record.

Notes: