EudraCT Results Form

Trial Information

A. Trial Identification

Full title of the trial

A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants

EudraCT Number	2018-001316-29
Sponsor Protocol Code	205801-003
ISRCTN Number	
ClinicalTrials.gov identifier (NCT Number)	
WHO Universal Trial Reference Number (UTRN)	

Other trial identifiers

Other identifier name	Other identifier code

B. Paediatric Regulatory Details

Is the trial part of an agreed Paediatric Investigation Plan (PIP)?	No
Paediatric Investigation Plan(s)	EMA Decision number of Paediatric Investigation Plan(s)
Enter the EMA paediatric Investigation plan	

number(s) (PIP) using the following format: EMEA-999999-PIP99-99, where 9 is a number (0-9 inclusive).

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

C. Sponsor Details

Name	Scientific Contact	Public Contact
Organisation name: GlaxoSmithKline	**Functional contact name:** GSK Response Center	**Functional contact name:** GSK Response Center
Street Address: 79 New Oxford Street	**Organisation name:** GlaxoSmithKline	**Organisation name:** GlaxoSmithKline
Town/City: London	**Country code:** 1	**Country code:** 1
Country: United Kingdom	**Phone Number:** 8664357343	**Phone Number:** 8664357343
Post code: WC1A 1DG	**Email address:** GSKClinicalSupportHD@gsk.com	**Email address:** GSKClinicalSupportHD@gsk.com

D. Results Analysis Stage

Analysis Stage	Final
Date of interim/Final Analysis	2024-10-24
Is this the analysis of the primary completion data?	No

Primary completion date

Global end of trial date reached?	Yes
Global end of trial date	2024-05-02
Was the trial ended prematurely?	Yes

E. General Information About Trial

Main objective of Trial	To determine the safety and tolerability of novel regimen(s)

The actual start date of recruitment must be the current date or a date in the past.

Actual Start date of Recruitment	2021-12-23
Long term follow up planned?	No
Long term follow up rationale	
Long term follow up duration	
Independent data monitoring committee (IDMC) involvement?	No
Protection of trial subjects	NA
Background therapy	
Evidence of comparator(s)	

F. Population of Trial Subjects

Subject number per country

Country	Actual number of subjects enrolled
Canada	14
France	11
Germany	2
Italy	16
Spain	14
United States	5
Total: worldwide	62
Total: EEA	43

Age group breakdown for Trial

Age Range	Actual number of subjects enrolled
In Utero	0
Pre-term 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)	31
From 65 years	
Elderly (From 65-84 years)	18
Elderly 85 years and over	13

Age Range	Actual number of subjects enrolled
Total	62

Subject Disposition

Subject Disposition

Recruitment Details

Pre-Assignment

Screening Details

This is a sub-study of the master study NCT03739710. This sub study was terminated due to low enrolment of participants. The study was planned to include two parts - Part 1 and Part 2. No participants from this sub study were enrolled in part 2 as study was terminated early.

Pre-Assignment Period

Periods

Overall Study (overall period)

Blinding Implementation Details:

Is this the baseline period? true

Mutually exclusive arms? true

Non-Mutual Exclusive Number of Subjects:

Allocation: Not Applicable

Blinding Used: Not-blind

Roles Blinded:

Started

Arm 4: Dostarlimab + Belrestotug [low dose (LD)] (Experimental) Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [high dose (HD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.
6	9	9	10	7

Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	Total *(=sum per row)*	
11	10	62 *(calculated)*	

Completed

Arm 4: Dostarlimab + Belrestotug [low dose (LD)] (Experimental) Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [high dose (HD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.
6 2 completed follow-up and 4 died	6 1 completed follow-up and 5 died	7 7 died	8 1 completed follow-up and 7 died	7 3 completed follow-up and 4 died
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of	Total *(=sum per row)*		

randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	
9 2 completed follow-up and 7 died	9 3 completed follow-up and 6 died	52 *(calculated)*

Reasons Not Completed

Lost to Follow-up

Arm 4: Dostarlimab + Belrestotug [low dose (LD)] (Experimental) Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [high dose (HD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-

		protocol-defined criteria are met.	defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.
0	0	0	1	0
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	Total *(=sum per row)*		
0	0	1 *(calculated)*		

Physician Decision

Arm 4: Dostarlimab + Belrestotug [low dose (LD)] (Experimental) Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV	Arm 4: Dostarlimab + Belrestotug [high dose (HD)] (Experimental) Participants with NSCLC were administered with 500 mg of	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD (Experimental) Participants with NSCLC received 500 mg dostarlimab	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab

approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.
0	0	0	0	0
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed	Total *(=sum per row)*		

	for PK/PD and received Nelistotug HD.	
0	1	1 *(calculated)*

Consent withdrawn by subject

Arm 4: Dostarlimab + Belrestotug [low dose (LD)] (Experimental) Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 4: Dostarlimab + Belrestotug [high dose (HD)] (Experimental) Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.
0	3	2	1	0
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD (Experimental) Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD (Experimental) Participants with NSCLC	Total *(=sum per row)*		

infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	
2	0	8 *(calculated)*

Reasons Joined

Products

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Dostarlimab + Belrestotug			Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Infusion	Intravenous use
Arm 4: Dostarlimab + Belrestotug [medium	Dostarlimab +			Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in	Infusion	Intravenous use

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
dose (MD)]	Belrestotug			combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.		
Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Dostarlimab + Belrestotug			Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	Infusion	Intravenous use
Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	Belrestotug + Dostarlimab + Nelistotug			Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	Infusion	Intravenous use
Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Belrestotug + Dostarlimab + Nelistotug			Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	Infusion	Intravenous use
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Belrestotug + Dostarlimab + Nelistotug			Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression,	Infusion	Intravenous use

Arm	Product Name	Product Code	Product Other Name	Dosage and Administration Details	Pharmaceutical Forms	Routes of Administration
				death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD.		
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	Belrestotug + Dostarlimab + Nelistotug			Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	Infusion	Intravenous use

Baseline Characteristics

Baseline Characteristics Information

The baseline Period is : Overall Study

How are baseline characteristics being reported?

Per Arm in the baseline period

Subject Analysis Sets

Reporting Groups

Reporting Group Title	Number of subjects	Description	Options
Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	6	Participants with Non-Small Cell Lung Cancer (NSCLC) were administered with 500 milligrams (mg) of Dostarlimab as IV infusion once every 3 weeks (Q3W) in combination with Belrestotug LD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	
Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	9	Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion Q3W in combination with Belrestotug MD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	
Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	9	Participants with NSCLC were administered with 500 mg of Dostarlimab as IV infusion once Q3W in combination with Belrestotug HD as IV infusion Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	
Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	10	Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug MD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	
Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	7	Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. Participants in this safety part were evaluated to determine the maximum tolerable dose tested.	
Arm5RandomizedPart: BelrestotugMD +	11	Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug LD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or	

Reporting Group Title	Number of subjects	Description	Options
Dostarlimab + NelistotugLD		until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for pharmacokinetics/pharmacodynamics (PK/PD) and received Nelistotug LD	
Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	10	Participants with NSCLC received 500 mg dostarlimab followed by Belrestotug MD and Nelistotug HD. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met. In this randomization part, participants were assessed for PK/PD and received Nelistotug HD.	

Age Characteristics

Title: Age Categorical

Description:

Unit: Participants

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
Overall number of baseline subjects	6	9	9	10
18 to >=85 years	6	9	9	10

Reporting Group Values	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	Total

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
Overall number of baseline subjects	7	11	10	28 (calculated)
18 to >=85 years	7	11	10	62
Total	7 (calculated)	11 (calculated)	10 (calculated)	62 (calculated)

Title: Age continuous

Description:

Unit:

Central Tendency Type:

Dispersion Type:

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]		Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]		Arm 4: Dostarlimab + Belrestotug [high dose (HD)]		Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	
Unit of measure ()		Low () High ()		Low () High ()		Low () High ()		Low () High ()

Reporting Group Values	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD		Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD		Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]		Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]		Arm 4: Dostarlimab + Belrestotug [high dose (HD)]		Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	
Unit of measure ()		Low () High ()		Low () High ()		Low () High ()		

Gender Characteristics

Title: Sex: Female, Male

Description:

Unit: Participants

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
Overall number of baseline subjects	6	9	9	10
Female	3	3	4	5
Male	3	6	5	5

Reporting Group Values	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	Total
Overall number of baseline subjects	7	11	10	28
Female	3	4	4	26

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
Male	4	7	6	36

Study Categorical Characteristics

Title: Race (NIH/OMB)

Description:

Unit: Participants

Reporting Group Values	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
Overall number of baseline subjects	6	9	9	10
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	1	0	0	0
White	4	7	8	10
Unknown or Not Reported	1	2	1	0

Reporting Group Values	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD	Total

Overall number of baseline subjects	7	11	10	28 (calculated)
Asian	1	0	2	3
Native Hawaiian or Other Pacific Islander	0	0	0	1
White	6	8	5	48
Unknown or Not Reported	0	3	3	10

Study Continuous Characteristics

End Points

Reporting Groups

Periods	Arms
Overall Study (overall period)	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]
	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]
	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]
	Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD
	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD
	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD
	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD

End Points

Primary: Part 1: Number of participants with any treatment emergent adverse events (TEAEs) and serious adverse events (SAEs) (Arm 4) - Safety Population

Countable or measurable? Countable

Description: An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose resulted in death, is life threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/ incapacity, is a congenital anomaly/ birth defect, other situations and is associated with liver injury or impaired liver function. SAEs are subset of AEs. A TEAE is any event that was not present prior to the initiation of study treatment or any event already present that worsens in either intensity or frequency following exposure to study treatment. AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable

Any TEAEs	6	9	8
Any SAEs	0	3	2

Primary: Part 1: Number of participants with any TEAEs and SAEs (Arm 5) - Safety Population

Countable or measurable? Countable

Description: An AE is any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that, at any dose resulted in death, is life threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/ incapacity, is a congenital anomaly/ birth defect, other situations and is associated with liver injury or impaired liver function. SAEs are subset of AEs. A TEAE is any event that was not present prior to the initiation of study treatment or any event already present that worsens in either intensity or frequency following exposure to study treatment. AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable

Any TEAEs	10	6	11	9
Any SAEs	3	3	3	3

Primary: Part 1: Number of participants with dose limiting toxicity (DLT) (Arm 4 and Arm 5) - DLT evaluable participants

Countable or measurable? Countable

Description: A DLT is an AE meeting criteria such as, hematologic toxicities of Grade (G) 4 neutropenia/anemia/thrombocytopenia (G3 if bleeding). Non-hematological toxicities include persistent G2 eye events, colitis/diarrhea (G2 unresolved to ≤ G1 within 7 days despite immunosuppressive therapy, G3 for ≥ 72 hours, any G4), G3 pneumonitis, rash (unresolved to ≤ G2 within 2 weeks despite treatment), hypersensitivity/IRR, liver events meeting Hy's Law criteria. G3 toxicity unresolved to ≤G1 or baseline within 3 days with supportive care, or any G4 toxicity. Exclusions include G3 events of electrolyte imbalances correctable within 72 hours without effects, nausea/vomiting/fatigue resolving within 7 days, lymphopenia, and enzyme elevations without pancreatitis. Considerations for DLTs include permanent treatment discontinuation, investigator/sponsor judgment-based events including post-observation period toxicities.

Time Frame: Up to 21 days

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**	**Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD**	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	9	9	10	7
Number of Subjects Analyzed:	4	4	4	7
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable

	0	0	0	1

Primary: Part 1: Number of participants requiring dose modifications (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Number of participants with dose modifications (missed doses, dose delays and infusion interruptions) is summarized.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Missed Doses	0	3	2
Dose Delays	0	1	1
Infusion Interruptions	0	1	1

Primary: Part 1: Number of participants requiring dose modifications (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Number of participants with dose modifications (missed doses, dose delays and infusion interruptions) is summarized.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Missed Doses	6	2	5	6
Dose Delays	1	0	0	0
Infusion Interruptions	0	2	0	0

Primary: Part 1: Number of participants with Eastern Cooperative Oncology Group (ECOG) Performance Status (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Performance Status was assessed using the ECOG scale (Grades 0-5), where 0: Fully active, able to carry on all pre-disease performance without restriction. Grade 1: Restricted in physically strenuous activity but ambulatory & able to carry out work of light or sedentary nature; Grade 2 - Ambulatory & capable of all self-care but unable to carry out any work activities. Up and about more than (>) 50% of waking hours; Grade 3 -Capable of only limited self-care, confined to bed or chair > 50% of waking hours; Grade 4 -Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair; Grade 5 -Dead. 88888 - 0 participant analysed for the mentioned timepoint.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Baseline, Grade 0	0	5	3
Baseline, Grade 1	6	4	6
Week 4, Grade 0	1	4	3
Week 4, Grade 1	3	3	4
Week 4, Grade 2	2	1	1
Week 7, Grade 0	1	2	1
Week 7, Grade 1	1	1	5
Week 10, Grade 0	1	2	1
Week 10, Grade 1	0	1	3

Week 13, Grade 0	1	1	1
Week 13, Grade 1	0	2	1
Week 16, Grade 0	1	1	1
Week 16, Grade 1	0	2	0
Week 19, Grade 0	1	0	1
Week 19, Grade 1	0	3	0
Week 22, Grade 0	1	0	0
Week 22, Grade 1	0	2	1
Week 25, Grade 0	88888	1	0
Week 25, Grade 1	88888	1	1
Week 28, Grade 0	88888	1	0
Week 28 Grade 1	88888	1	1
Week 31, Grade 0	88888	1	1
Week 34, Grade 0	88888	88888	1
Week 37, Grade 0	88888	1	1
Week 40, Grade 0	88888	1	88888
Week 43, Grade 0	88888	1	88888
Week 46, Grade 0	88888	1	88888
Week 49, Grade 0	88888	1	88888
Week 52, Grade 1	88888	1	88888
Week 55, Grade 1	88888	1	88888
Week 58, Grade 0	88888	1	88888
Week 61, Grade 0	88888	1	88888
Week 64, Grade 1	88888	1	88888

Week 67, Grade 1	88888	1	88888
Week 70, Grade 1	88888	1	88888
Treatment Discontinuation, Grade 0	1	1	0
Treatment Discontinuation, Grade 1	2	5	4
Treatment Discontinuation, Grade 2	1	1	1
Treatment Discontinuation, Grade 3	2	0	1

Primary: Part 1: Number of participants with Eastern Cooperative Oncology Group (ECOG) Performance Status (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Performance Status was assessed using the ECOG scale (Grades 0-5), where 0: Fully active, able to carry on all pre-disease performance without restriction. Grade 1: Restricted in physically strenuous activity but ambulatory & able to carry out work of light or sedentary nature; Grade 2 - Ambulatory & capable of all self-care but unable to carry out any work activities. Up and about more than (>) 50% of waking hours; Grade 3 -Capable of only limited self-care, confined to bed or chair > 50% of waking hours; Grade 4 -Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair; Grade 5 -Dead. 88888 - 0 participant analysed for the mentioned timepoint.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10

Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Baseline, Grade 0	4	2	7	1
Baseline, Grade 1	6	5	4	9
Week 4, Grade 0	4	1	5	1
Week 4, Grade 1	4	5	6	8
Week 4, Grade 2	2	0	0	0
Week 7, Grade 0	3	2	3	1
Week 7, Grade 1	3	2	4	6
Week 7, Grade 2	2	0	1	0
Week 10, Grade 0	1	2	3	1
Week 10, Grade 1	5	1	3	3
Week 10, Grade 2	1	0	0	0
Week 13, Grade 0	2	2	2	0
Week 13, Grade 1	3	0	2	4
Week 16, Grade 0	2	2	2	1
Week 16, Grade 1	2	0	2	2
Week 19, Grade 0	3	2	2	0
Week 19, Grade 1	2	0	1	2
Week 22, Grade 0	2	1	2	0
Week 22, Grade 1	2	1	1	1
Week 25, Grade 0	2	1	1	0
Week 25, Grade 1	1	1	2	1

Week 28, Grade 0	2	0	1	0
Week 28, Grade 1	0	1	2	1
Week 31, Grade 0	2	1	1	88888
Week 34, Grade 0	2	1	0	88888
Week 37, Grade 0	1	88888	1	88888
Week 37, Grade 1	1	88888	0	88888
Week 40, Grade 0	2	88888	0	88888
Week 40, Grade 1	0	88888	1	88888
Week 43, Grade 0	1	88888	0	88888
Week 43, Grade 1	0	88888	1	88888
Week 46, Grade 0	1	88888	0	88888
Week 46, Grade 1	0	88888	1	88888
Week 49, Grade 0	1	88888	0	88888
Week 49, Grade 2	0	88888	1	88888
Week 52, Grade 0	1	88888	88888	88888
Week 55, Grade 0	1	88888	88888	88888
Week 58, Grade 0	1	88888	88888	88888
Treatment Discontinuation, Grade 0	1	1	4	1
Treatment Discontinuation, Grade 1	5	6	4	5
Treatment Discontinuation, Grade 2	1	0	1	1
Treatment Discontinuation, Grade 3	1	0	0	0

Primary: Part 1: Number of participants with worst-case post baseline Increase From Baseline in

Vital Signs (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Vital signs including systolic blood pressure (SBP), diastolic BP (DBP), pulse rate (PR) and body temperature (BT) were measured for the participants. DBP: Grade 0 (<80 millimeters of mercury [mmHg]), Grade 1 (80-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (>=100 mmHg); SBP: Grade 0 (<120 mmHg), Grade 1 (120-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (>=160 mmHg); PR categories include: 'Decrease to < 60 beats per minutes [bpm]', 'Change to Normal' or 'No Change', and 'Increase to >100 bpm'; BT categories include 'Decrease to <=35 degrees Celsius °C', 'Change to Normal' or 'No Change', and 'Increase to >=38 °C'. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Diastolic Blood Pressure, Any Grade Increase	0	2	2
Diastolic Blood Pressure, Increase to Grade 2	0	1	0
Diastolic Blood Pressure, Increase to Grade 3	0	0	1
Systolic Blood Pressure, Any Grade Increase	1	2	3

Systolic Blood Pressure, Increase to Grade 2	1	2	2
Systolic Blood Pressure, Increase to Grade 3	0	0	1
Heart Rate, Decrease to <60 bpm	0	0	0
Heart Rate, Change to Normal or No Change	4	7	6
Heart Rate, Increase to >100 bpm	2	2	2
Temperature, Decrease to <=35 C	0	0	0
Temperature, Change to Normal or No Change	6	9	6
Temperature, Increase to >=38 C	0	0	2

Primary: Part 1: Number of participants with worst-case post baseline Increase From Baseline in Vital Signs (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Vital signs including systolic blood pressure (SBP), diastolic BP (DBP), pulse rate (PR) and body temperature (BT) were measured for the participants. DBP: Grade 0 (<80 millimeters of mercury [mmHg]), Grade 1 (80-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (>=100 mmHg); SBP: Grade 0 (<120 mmHg), Grade 1 (120-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (>=160 mmHg); PR categories include: 'Decrease to < 60 beats per minutes [bpm]', 'Change to Normal' or 'No Change', and 'Increase to >100 bpm'; BT categories include 'Decrease to <=35 degrees Celsius °C', 'Change to Normal' or 'No Change', and 'Increase to >=38 °C'. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part:	**Overall Study Arm 5 SafetyPart:**	**Overall Study Arm5RandomizedPart:**	**Overall Study Arm5RandomizedPart:**

	BelrestotugMD + Dostarlimab + NelistotugMD	BelrestotugMD + Dostarlimab + NelistotugHD	BelrestotugMD + Dostarlimab + NelistotugLD	BelrestotugMD + Dostarlimab + NelistotugHD
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Diastolic Blood Pressure, Any Grade Increase	5	1	4	5
Diastolic Blood Pressure, Increase to Grade 2	3	0	1	0
Diastolic Blood Pressure, Increase to Grade 3	0	0	0	0
Systolic Blood Pressure, Any Grade Increase	4	2	5	4
Systolic Blood Pressure, Increase to Grade 2	1	1	2	1
Systolic Blood Pressure, Increase to Grade 3	1	0	0	2
Heart Rate, Decrease to <60 bpm	0	0	0	0
Heart Rate, Change to Normal or No Change	7	7	9	7
Heart Rate, Increase to >100 bpm	3	0	2	2
Temperature, Decrease to <=35 C	0	0	0	0
Temperature, Change to Normal or No Change	10	6	11	9
Temperature, Increase to >=38 C	0	1	0	0

Primary: Part 1: Number of participants who received Concomitant medication (Arm 4) - Intent-to-treat Population

Countable or measurable? Countable

Description: Number of participants who received Concomitant medications is summarized.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
	6	9	9

Primary: Part 1: Number of participants who received Concomitant medication (Arm 5) - Intent-to-treat Population

Countable or measurable? Countable

Description: Number of participants who received Concomitant medications is summarized.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
	10	7	11	10

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline Electrocardiogram (ECG) findings (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Number of participants with worst-case post baseline (WCPB) from baseline ECG findings is summarized as clinically significant. Data is summarized as Normal, Abnormal - Not Clinically Significant (NCS) and Abnormal - Clinically Significant (CS). Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Baseline, Normal	4	2	4
Baseline, Abnormal - NCS	2	6	3
Baseline, Abnormal - CS	0	0	2
WCPB, Normal	2	2	3
WCPB, Abnormal - NCS	3	1	2
WCPB, Abnormal - CS	0	1	3

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline ECG findings (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Number of participants with worst-case post baseline (WCPB) from baseline ECG findings is summarized as clinically significant. Data is summarized as Normal, Abnormal - Not Clinically Significant (NCS) and Abnormal - Clinically Significant (CS). Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Baseline, Normal	5	5	5	7
Baseline, Abnormal - NCS	4	1	5	2
Baseline, Abnormal - CS	1	1	1	1
WCPB, Normal	0	5	4	4
WCPB, Abnormal - NCS	7	2	4	5
WCPB, Abnormal - CS	3	0	3	0

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline in QTcF Interval (Arm 4) - Safety Population

Countable or measurable? Countable

Description: The QTcF values based on Fridericia formula were rounded to the integer and the values are categorized into the following ranges, inclusively: Grade 0 (<450 millisecond (msec)), Grade 1 (≥450-≤480 msec), Grade 2 (≥481-≤500 msec), and Grade 3 (≥501 msec). Missing baseline grades were assumed to be Grade 0. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Baseline, Grade 0	4	6	8
Baseline, Grade 1	1	0	0
Baseline, Grade 2	0	1	1
Baseline, Grade 3	1	1	0
WCPB, No Grade Increase	4	4	7
WCPB, Increase to Grade 1	1	0	1

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline in QTcF Interval (Arm 5) - Safety Population

Countable or measurable? Countable

Description: The QTcF values based on Fridericia formula were rounded to the integer and the values are categorized into the following ranges, inclusively: Grade 0 (<450 millisecond (msec)), Grade 1 (≥450-≤480 msec), Grade 2 (≥481-≤500 msec), and Grade 3 (≥501 msec). Missing baseline grades were assumed to be Grade 0. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Baseline, Grade 0	10	6	10	9
Baseline, Grade 1	0	1	1	0
Baseline, Grade 2	0	0	0	0
Baseline, Grade 3	0	0	0	0
WCPB, No Grade Increase	10	5	11	8
WCPB, Increase to Grade 2	0	2	0	0
WCPB, Increase to Grade 3	0	0	0	1

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline in Left ventricular ejection fraction (LVEF) (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Number of participants with worst case post-baseline in LVEF from baseline is summarized as 'any decrease (>0%-<10% Decrease, 10%-19% Decrease, >=20% Decrease)', '>=10% Decrease and >= Lower limit of normal (LLN)', '>=10% Decrease and < LLN', '>=20% Decrease and >= LLN' and '>=20% Decrease and < LLN' . An increase is defined as an increase in grade relative to Baseline grade. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups	
	Overall Study **Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**
Number of subjects that started the Arm:	9
Number of Subjects Analyzed:	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)	
	Countable
No change or any increase	1
Any Decrease	0
>=10% Decrease and >= LLN	0
>=10% Decrease and < LLN	0
>=20% Decrease and >= LLN	0

>=20% Decrease and < LLN	0

Primary: Part 1: Number of participants with worst-case post baseline relative to baseline in Left ventricular ejection fraction (LVEF) (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Number of participants with worst case post-baseline in LVEF from baseline is summarized as 'any decrease (>0%-<10% Decrease, 10%-19% Decrease, >=20% Decrease)', '>=10% Decrease and >= Lower limit of normal (LLN)', '>=10% Decrease and < LLN', '>=20% Decrease and >= LLN' and '>=20% Decrease and < LLN' . An increase is defined as an increase in grade relative to Baseline grade. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	11	10
Number of Subjects Analyzed:	10	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
No change or any increase	2	0	0
Any Decrease	0	2	1

>=10% Decrease and >= LLN	0	0	0
>=10% Decrease and < LLN	0	0	0
>=20% Decrease and >= LLN	0	0	0
>=20% Decrease and < LLN	0	0	0

Primary: Part 1: Number of participants with Worst Case Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for the analysis of hematology parameters and are categorized in alignment with Common Terminology Criteria for Adverse Events (CTCAE) version 5 as Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; and Grade 4: life-threatening consequences. Higher grade indicates greater severity. An increase in grade is defined relative to the Baseline grade. Participants with missing baseline values are assumed to have baseline value of grade 0. Any worst-case post baseline increase in grade along with any increase to a maximum grade of 3 and 4 is summarized. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			

	Countable	Countable	Countable
Eosinophils, Any Grade Increase	1	2	0
Eosinophils, Increase to Grade 3	0	0	0
Eosinophils, Increase to Grade 4	0	0	0
Lymphocyte count decreased,, Any Grade Increase	1	6	6
Lymphocyte count decreased, Increase to Grade 3	0	1	2
Lymphocyte count decreased, Increase to Grade 4	0	0	0
Lymphocyte count increased, Any Grade Increase	0	0	0
Lymphocyte count increased, Increase to Grade 3	0	0	0
Lymphocyte count increased, Increase to Grade 4	0	0	0
Platelet count decreased, Any Grade Increase	0	1	0
Platelet count decreased, Increase to Grade 3	0	0	0
Platelet count decreased, Increase to Grade 4	0	0	0
White blood cell decreased, Any Grade Increase	0	1	2
White blood cell decreased, Increase to Grade 3	0	0	0
White blood cell decreased, Increase to Grade 4	0	0	0
Anemia, Any Grade Increase	4	3	1
Anemia, Increase to Grade 3	0	1	0

Anemia, Increase to Grade 4	0	0	0
Hemoglobin increased, Any Grade Increase	0	0	0
Hemoglobin increased, Increase to Grade 3	0	0	0
Hemoglobin increased, Increase to Grade 4	0	0	0
Neutrophil count decreased, Any Grade Increase	0	0	0
Neutrophil count decreased, Increase to Grade 3	0	0	0
Neutrophil count decreased, Increase to Grade 4	0	0	0

Primary: Part 1: Number of participants with Worst Case Hematology Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for the analysis of hematology parameters and are categorized in alignment with Common Terminology Criteria for Adverse Events (CTCAE) version 5 as Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; and Grade 4: life-threatening consequences. Higher grade indicates greater severity. An increase in grade is defined relative to the Baseline grade. Participants with missing baseline values are assumed to have baseline value of grade 0. Any worst-case post baseline increase in grade along with any increase to a maximum grade of 3 and 4 is summarized. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD +	**Overall Study Arm 5 SafetyPart: BelrestotugMD +**	**Overall Study Arm5RandomizedPart:**	**Overall Study Arm5RandomizedPart:**

	Dostarlimab + NelistotugMD	Dostarlimab + NelistotugHD	BelrestotugMD + Dostarlimab + NelistotugLD	BelrestotugMD + Dostarlimab + NelistotugHD
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Eosinophils, Any Grade Increase	1	2	3	3
Eosinophils, Increase to Grade 3	0	0	0	0
Eosinophils, Increase to Grade 4	0	0	0	0
Lymphocyte count decreased, Any Grade Increase	8	4	8	8
Lymphocyte count decreased, Increase to Grade 3	3	1	4	3
Lymphocyte count decreased, Increase to Grade 4	1	0	1	0
Lymphocyte count increased, Any Grade Increase	0	0	0	0
Lymphocyte count increased, Increase to Grade 3	0	0	0	0
Lymphocyte count increased, Increase to Grade 4	0	0	0	0
Platelet count decreased, Any Grade Increase	1	0	2	0
Platelet count decreased, Increase to Grade 3	0	0	0	0
Platelet count decreased, Increase to Grade 4	0	0	1	0

White blood cell decreased, Any Grade Increase	0	1	0	1
White blood cell decreased, Increase to Grade 3	0	0	0	0
White blood cell decreased, Increase to Grade 4	0	0	0	0
Anemia, Any Grade Increase	6	2	4	4
Anemia, Increase to Grade 3	1	0	1	0
Anemia, Increase to Grade 4	0	0	0	0
Hemoglobin increased, Any Grade Increase	2	0	0	0
Hemoglobin increased, Increase to Grade 3	2	0	0	0
Hemoglobin increased, Increase to Grade 4	0	0	0	0
Neutrophil count decreased, Any Grade Increase	0	1	1	0
Neutrophil count decreased, Increase to Grade 3	0	0	1	0
Neutrophil count decreased, Increase to Grade 4	0	0	0	0

Primary: Part 1: Number of participants with Worst Case clinical chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for the analysis of clinical chemistry parameters and are categorized in alignment with Common Terminology Criteria for Adverse Events (CTCAE) version 5 as Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; and Grade 4: life-threatening consequences. Higher grade indicates greater severity. An increase in grade is defined relative to the Baseline grade. Participants with missing baseline values are assumed to have baseline value of grade 0. Any worst-case post baseline increase in grade along with any increase to a maximum grade of 3 and 4 is summarized. Baseline is defined as the latest pre-dose assessment with a non-

missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline. 88888-0 participant analysed for the mentioned timepoint.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
aPTT, Any Grade Increase	88888	88888	88888
aPTT, Increase to Grade 3	88888	88888	88888
aPTT, Increase to Grade 4	88888	88888	88888
Glucose, Any Grade Increase	0	2	0
Glucose, Increase to Grade 3	0	0	0
Glucose, Increase to Grade 4	0	0	0
INR increased, Any Grade Increase	88888	88888	88888
INR increased, Increase to Grade 3	88888	88888	88888
INR increased, Increase to Grade 4	88888	88888	88888
Alkaline phosphatase (AP), Any Grade Increase	1	3	1
AP, Increase to Grade 3	0	0	0

AP, Increase to Grade 4	0	0	0
ALT, Any Grade Increase	1	2	0
ALT, Increase to Grade 3	0	0	0
ALT, Increase to Grade 4	0	0	0
AST, Any Grade Increase	1	1	0
AST, Increase to Grade 3	0	0	0
AST, Increase to Grade 4	0	0	0
Bilirubin, Any Grade Increase	0	1	0
Bilirubin, Increase to Grade 3	0	0	0
Bilirubin, Increase to Grade 4	0	0	0
Creatinine, Any Grade Increase	2	3	3
Creatinine, Increase to Grade 3	0	0	0
Creatinine, Increase to Grade 4	0	0	0
Potassium, Any Grade Increase	0	2	1
Potassium, Increase to Grade 3	0	0	0
Potassium, Increase to Grade 4	0	0	0
Lactate Dehydrogenase, Any Grade Increase	1	2	3
Lactate Dehydrogenase, Increase to Grade 3	0	0	0
Lactate Dehydrogenase, Increase to Grade 4	0	0	0
Sodium, Any Grade Increase	0	0	0
Sodium, Increase to Grade 3	0	0	0
Sodium, Increase to Grade 4	0	0	0

Albumin, Any Grade Increase	4	3	4
Albumin, Increase to Grade 3	0	0	0
Albumin, Increase to Grade 4	0	0	0

Primary: Part 1: Number of participants with Worst Case clinical chemistry Results by Maximum Grade Increase Post-Baseline Relative to Baseline (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for the analysis of clinical chemistry parameters and are categorized in alignment with Common Terminology Criteria for Adverse Events (CTCAE) version 5 as Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; and Grade 4: life-threatening consequences. Higher grade indicates greater severity. An increase in grade is defined relative to the Baseline grade. Participants with missing baseline values are assumed to have baseline value of grade 0. Any worst-case post baseline increase in grade along with any increase to a maximum grade of 3 and 4 is summarized. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline. 88888-0 participant analysed for the mentioned timepoint.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				

	Countable	Countable	Countable	Countable
aPTT, Any Grade Increase	88888	88888	88888	88888
aPTT, Increase to Grade 3	88888	88888	88888	88888
aPTT, Increase to Grade 4	88888	88888	88888	88888
Glucose, Any Grade Increase	0	0	0	2
Glucose, Increase to Grade 3	0	0	0	0
Glucose, Increase to Grade 4	0	0	0	0
INR increased, Any Grade Increase	88888	88888	88888	88888
INR increased, Increase to Grade 3	88888	88888	88888	88888
INR increased, Increase to Grade 4	88888	88888	88888	88888
AP, Any Grade Increase	3	1	1	2
AP, Increase to Grade 3	0	0	0	0
AP, Increase to Grade 4	0	0	0	0
ALT, Any Grade Increase	1	0	1	3
ALT, Increase to Grade 3	0	0	0	1
ALT, Increase to Grade 4	0	0	0	0
AST, Any Grade Increase	0	2	3	2
AST, Increase to Grade 3	0	0	0	0
AST, Increase to Grade 4	0	0	0	0
Bilirubin, Any Grade Increase	2	0	2	0
Bilirubin, Increase to Grade 3	0	0	0	0
Bilirubin, Increase to Grade 4	0	0	0	0
Creatinine, Any Grade Increase	3	3	3	4
Creatinine, Increase to Grade 3	1	0	0	1

Creatinine, Increase to Grade 4	0	0	0	0
Potassium, Any Grade Increase	1	0	2	2
Potassium, Increase to Grade 3	0	0	0	0
Potassium, Increase to Grade 4	0	0	0	0
Lactate Dehydrogenase, Any Grade Increase	2	0	4	4
Lactate Dehydrogenase, Increase to Grade 3	0	0	0	0
Lactate Dehydrogenase, Increase to Grade 4	0	0	0	0
Sodium, Any Grade Increase	0	0	0	0
Sodium, Increase to Grade 3	0	0	0	0
Sodium, Increase to Grade 4	0	0	0	0
Albumin, Any Grade Increase	6	4	4	1
Albumin, Increase to Grade 3	0	1	0	0
Albumin, Increase to Grade 4	0	0	0	0

Primary: Part 1: Number of participants with Worst Case change post-baseline in clinical chemistry parameters (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for analysis of clinical chemistry. The summaries of worst-case post baseline (WCPB) from baseline (B) with respect to normal range was analyzed. Data is presented as “XXX B YYY, WCPB YYY”, where XXX denotes lab parameter and YYY is high/normal/low. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable
Calcium, B High, WCPB High	0	1	1
Calcium, B High, WCPB Normal	0	0	0
Calcium, B High, WCPB Low	0	0	0
Calcium, B Normal, WCPB High	2	0	1
Calcium, B Normal, WCPB Normal	4	0	5
Calcium, B Normal, WCPB Low	0	0	1
Calcium, B Low, WCPB High	0	2	0
Calcium, B Low, WCPB Normal	0	7	0
Calcium, B Low, WCPB Low	0	0	0
Lipase, B High, WCPB High	0	0	0
Lipase, B High, WCPB Normal	0	0	0
Lipase, B High, WCPB Low	0	0	0
Lipase, B Normal, WCPB High	1	1	2
Lipase, B Normal, WCPB Normal	4	5	5

Lipase, B Normal, WCPB Low	0	0	0
Lipase, B Low, WCPB High	0	0	0
Lipase, B Low, WCPB Normal	0	1	0
Lipase, B Low, WCPB Low	0	0	0
Amylase, B High, WCPB High	0	1	0
Amylase, B High, WCPB Normal	0	0	0
Amylase, B High, WCPB Low	0	0	0
Amylase, B Normal, WCPB High	0	0	1
Amylase, B Normal, WCPB Normal	4	4	6
Amylase, B Normal, WCPB Low	1	1	0
Amylase, B Low, WCPB High	0	0	0
Amylase, B Low, WCPB Normal	0	0	0
Amylase, B Low, WCPB Low	0	0	0
Urea, B High, WCPB High	0	2	0
Urea, B High, WCPB Normal	0	0	0
Urea, B High, WCPB Low	0	0	0
Urea, B Normal, WCPB High	1	1	0
Urea, B Normal, WCPB Normal	1	1	5
Urea, B Normal, WCPB Low	1	0	1
Urea, B Low, WCPB High	0	0	0
Urea, B Low, WCPB Normal	1	0	0
Urea, B Low, WCPB Low	0	1	0
Free Triiodothyronine (T3), B High, WCPB High	0	0	0
T3, B High, WCPB Normal	0	0	0

T3, B High, WCPB Low	0	0	0
T3, B Normal, WCPB High	0	0	1
T3, B Normal, WCPB Normal	1	2	4
T3, B Normal, WCPB Low	1	2	1
T3, B Low, WCPB High	0	0	0
T3, B Low, WCPB Normal	0	0	0
T3, B Low, WCPB Low	0	0	0
Free Thyroxine (T4), B High, WCPB High	0	0	0
T4, B High, WCPB Normal	0	0	0
T4, B High, WCPB Low	0	0	0
T4, B Normal, WCPB High	0	0	0
T4, B Normal, WCPB Normal	4	6	5
T4, B Normal, WCPB Low	0	1	0
T4, B Low, WCPB High	0	0	1
T4, B Low, WCPB Normal	0	0	0
T4, B Low, WCPB Low	0	0	0
Troponin I, B High, WCPB High	0	1	0
Troponin I, B High, WCPB Normal	0	0	0
Troponin I, B High, WCPB Low	0	0	0
Troponin I, B Normal, WCPB High	0	2	0
Troponin I, B Normal, WCPB Normal	1	0	3
Troponin I, B Normal, WCPB Low	0	0	0
Troponin I, B Low, WCPB High	0	0	0
Troponin I, B Low, WCPB Normal	0	0	0

Troponin I, B Low, WCPB Low	0	0	0
Thyrotropin, B High, WCPB High	1	0	0
Thyrotropin, B High, WCPB Normal	0	0	0
Thyrotropin, B High, WCPB Low	0	0	0
Thyrotropin, B Normal, WCPB High	0	1	0
Thyrotropin, B Normal, WCPB Normal	3	4	2
Thyrotropin, B Normal, WCPB Low	0	1	5
Thyrotropin, B Low, WCPB High	0	0	0
Thyrotropin, B Low, WCPB Normal	1	0	0
Thyrotropin, B Low, WCPB Low	0	0	0

Primary: Part 1: Number of participants with Worst Case change post-baseline in clinical chemistry parameters (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Blood samples were collected for analysis of clinical chemistry. The summaries of worst-case post baseline (WCPB) from baseline (B) with respect to normal range was analyzed. Data is presented as “XXX B YYY, WCPB YYY”, where XXX denotes lab parameter and YYY is high/normal/low. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits. Worst Case Post-Baseline includes all scheduled and unscheduled visits post baseline.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD +	**Overall Study Arm 5 SafetyPart: BelrestotugMD +**	**Overall Study Arm5RandomizedPart:**	**Overall Study Arm5RandomizedPart:**

	Dostarlimab + NelistotugMD	Dostarlimab + NelistotugHD	BelrestotugMD + Dostarlimab + NelistotugLD	BelrestotugMD + Dostarlimab + NelistotugHD
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				
	Countable	Countable	Countable	Countable
Calcium, B High, WCPB High	0	0	0	0
Calcium, B High, WCPB Normal	0	0	0	1
Calcium, B High, WCPB Low	0	0	0	0
Calcium, B Normal, WCPB High	0	1	0	0
Calcium, B Normal, WCPB Normal	9	5	7	8
Calcium, B Normal, WCPB Low	1	1	3	1
Calcium, B Low, WCPB High	0	0	0	0
Calcium, B Low, WCPB Normal	0	0	1	0
Calcium, B Low, WCPB Low	0	0	0	0
Lipase, B High, WCPB High	2	0	0	0
Lipase, B High, WCPB Normal	0	0	0	0
Lipase, B High, WCPB Low	0	0	0	0
Lipase, B Normal, WCPB High	0	1	2	3
Lipase, B Normal, WCPB Normal	5	2	6	6
Lipase, B Normal, WCPB Low	0	0	1	0
Lipase, B Low, WCPB High	0	0	0	0
Lipase, B Low, WCPB Normal	0	0	0	0
Lipase, B Low, WCPB Low	0	0	1	0

Amylase, B High, WCPB High	1	1	1	1
Amylase, B High, WCPB Normal	0	0	0	0
Amylase, B High, WCPB Low	0	0	0	0
Amylase, B Normal, WCPB High	0	0	2	2
Amylase, B Normal, WCPB Normal	6	1	7	6
Amylase, B Normal, WCPB Low	0	0	0	0
Amylase, B Low, WCPB High	0	0	0	0
Amylase, B Low, WCPB Normal	0	1	0	0
Amylase, B Low, WCPB Low	0	0	0	0
Urea, B High, WCPB High	2	1	0	0
Urea, B High, WCPB Normal	0	0	0	0
Urea, B High, WCPB Low	0	0	0	0
Urea, B Normal, WCPB High	1	1	2	4
Urea, B Normal, WCPB Normal	2	4	3	3
Urea, B Normal, WCPB Low	1	0	1	1
Urea, B Low, WCPB High	0	0	0	0
Urea, B Low, WCPB Normal	0	0	0	0
Urea, B Low, WCPB Low	0	0	0	0
Free Triiodothyronine (T3), B High, WCPB High	0	0	1	0
T3, B High, WCPB Normal	0	0	0	0
T3, B High, WCPB Low	0	0	0	0
T3, B Normal, WCPB High	1	0	1	0
T3, B Normal, WCPB Normal	3	3	6	8
T3, B Normal, WCPB Low	1	0	1	1

T3, B Low, WCPB High	0	0	0	0
T3, B Low, WCPB Normal	0	0	0	0
T3, B Low, WCPB Low	2	1	0	0
Free Thyroxine (T4), B High, WCPB High	0	1	0	1
T4, B High, WCPB Normal	0	0	0	0
T4, B High, WCPB Low	0	0	0	0
T4, B Normal, WCPB High	0	0	1	0
T4, B Normal, WCPB Normal	7	3	7	8
T4, B Normal, WCPB Low	1	0	1	0
T4, B Low, WCPB High	0	0	0	0
T4, B Low, WCPB Normal	0	0	0	0
T4, B Low, WCPB Low	0	0	0	0
Troponin I, B High, WCPB High	0	0	0	0
Troponin I, B High, WCPB Normal	0	0	0	0
Troponin I, B High, WCPB Low	0	0	0	0
Troponin I, B Normal, WCPB High	0	0	1	0
Troponin I, B Normal, WCPB Normal	2	1	5	6
Troponin I, B Normal, WCPB Low	0	0	0	0
Troponin I, B Low, WCPB High	0	0	0	0
Troponin I, B Low, WCPB Normal	0	0	0	0
Troponin I, B Low, WCPB Low	0	0	0	0
Thyrotropin, B High, WCPB High	2	1	1	0
Thyrotropin, B High, WCPB Normal	0	0	0	1
Thyrotropin, B High, WCPB Low	0	0	0	0

Thyrotropin, B Normal, WCPB High	2	1	1	0
Thyrotropin, B Normal, WCPB Normal	5	3	5	7
Thyrotropin, B Normal, WCPB Low	0	0	2	1
Thyrotropin, B Low, WCPB High	0	0	0	0
Thyrotropin, B Low, WCPB Normal	0	0	1	0
Thyrotropin, B Low, WCPB Low	0	0	0	0

Primary: Part 1: Number of participants with Worst-Case Urinalysis Results Post-Baseline Relative to Baseline (Arm 4) - Safety Population

Countable or measurable? Countable

Description: Urinalysis was performed. Participants with missing value at baseline are assumed to be negative at baseline. All increases are from baseline. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

Time Frame: Up to approximately 97 weeks

Units: Participants

Percentage:

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9
Comment: (The comment is mandatory when the number of subjects analysed is zero)			
	Countable	Countable	Countable

Occult Blood, No Change/Decreased	4	6	7
Occult Blood, Any Increase	1	1	1
Occult Blood, Unknown	0	0	0
Protein, No Change/Decreased	3	2	7
Protein, Any Increase	2	4	1
Protein, Unknown	0	1	0

Primary: Part 1: Number of participants with Worst-Case Urinalysis Results Post-Baseline Relative to Baseline (Arm 5) - Safety Population

Countable or measurable? Countable

Description: Urinalysis was performed. Participants with missing value at baseline are assumed to be negative at baseline. All increases are from baseline. Baseline is defined as the latest pre-dose assessment with a non-missing value, including those from unscheduled visits.

Time Frame: Up to approximately 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				

	Countable	Countable	Countable	Countable
Occult Blood, No Change/Decreased	4	5	6	6
Occult Blood, Any Increase	4	0	5	2
Occult Blood, Unknown	2	1	0	0
Protein, No Change/Decreased	3	5	5	7
Protein, Any Increase	5	1	6	1
Protein, Unknown	0	0	0	0

Primary: Part 2: Overall survival (OS)

Countable or measurable? Measurable

Description: OS was defined as the interval from date of randomization to the date of death, irrespective of the cause of death. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to approximately 107 weeks

Measure Type: Median

Precision/Dispersion Type: Full Range (min-max)

Units: Months

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:

Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 1: Objective response rate (ORR) (Arm 4) - ITT population

Countable or measurable?	Measurable
Description:	ORR was defined as the percentage of participants with a best overall confirmed Complete response (CR) or Partial response (PR) at any time as per disease-specific criteria per RECIST version 1.1. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline).
Time Frame:	Up to approximately 97 weeks
Measure Type:	Number
Precision/Dispersion Type:	Confidence Interval
Units:	Percentage of Participants
Percentage:	95

Arm Reporting Groups			
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**
Number of subjects that started the Arm:	6	9	9
Number of Subjects Analyzed:	6	9	9

Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)
	0	0.0 to 45.9	0	0.0 to 33.6	0	0.0 to 33.6

Secondary: Part 1: Objective response rate (ORR) (Arm 5) - ITT population

Countable or measurable? Measurable

Description: ORR was defined as the percentage of participants with a best overall confirmed Complete response (CR) or Partial response (PR) at any time as per disease-specific criteria per RECIST version 1.1. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline).

Time Frame: Up to approximately 107 weeks

Measure Type: Number

Precision/Dispersion Type: Confidence Interval

Units: Percentage of Participants

Percentage: 95

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that	10	7	11	10

started the Arm:								
Number of Subjects Analyzed:	10		7		11		10	
Comment: (The comment is mandatory when the number of subjects analysed is zero)								
	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)
	0	0.0 to 30.8	0	0.0 to 41.0	9	0.2 to 41.3	0	0.0 to 30.8

Secondary: Part 1: Disease control rate (DCR) (Arm 4) - ITT population

Countable or measurable?	Measurable
Description:	DCR is defined as the percentage of participants with a confirmed CR + PR at any time, plus SD =>12 weeks as per RECIST v1.1. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). Stable Disease (SD) was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease.
Time Frame:	Up to approximately 97 weeks
Measure Type:	Number
Precision/Dispersion Type:	Confidence Interval
Units:	Percentage of Participants
Percentage:	95

Arm Reporting Groups						
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]		**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**		**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**	
Number of subjects that started the Arm:	6		9		9	
Number of Subjects Analyzed:	6		9		9	
Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)
	17	0.4 to 64.1	22	2.8 to 60.0	11	0.3 to 48.2

Secondary: Part 1: Disease control rate (DCR) (Arm 5) - ITT population

Countable or measurable? Measurable

Description: DCR is defined as the percentage of participants with a confirmed CR + PR at any time, plus SD =>12 weeks as per RECIST v1.1. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). Stable Disease (SD) was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease.

Time Frame: Up to approximately 107 weeks

Measure Type: Number

Precision/Dispersion Type: Confidence Interval

Units: Percentage of Participants

Percentage: 95

Arm Reporting Groups								
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD		**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**	
Number of subjects that started the Arm:	10		7		11		10	
Number of Subjects Analyzed:	10		7		11		10	
Comment: (The comment is mandatory when the number of subjects analysed is zero)								
	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)	Number	Confidence Interval (95%)
	40	12.2 to 73.8	14	0.4 to 57.9	27	6.0 to 61.0	0	0.0 to 30.8

Secondary: Part 1: Maximum observed concentration (Cmax) and Minimum observed concentration (Cmin) of Belrestotug (Arm 4) - PK population

Countable or measurable? Measurable

Description: Blood samples were collected for pharmacokinetic analysis of Belrestotug. Pharmacokinetic (PK) population included all participants from the ITT Population from whom a blood sample is obtained and analyzed for PK concentration. PK parameters were only calculated for treatment cycles in which sufficient data were available to do so.

Time Frame: Up to 21 days (Cycle 1)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: Microgram/ millilitre (ug/mL)

Percentage:

Arm Reporting Groups						
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]		**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**		**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**	
Number of subjects that started the Arm:	6		9		9	
Number of Subjects Analyzed:	6		9		9	
Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Cmax	88.470	92.2653	118.762	46.4217	271.835	77.5244
Cmin	9.412	5.6264	22.091	8.4224	44.350	24.4184

Secondary: Part 1: Maximum observed concentration (Cmax) and Minimum observed concentration (Cmin) of Belrestotug (Arm 5) - PK population

Countable or measurable? Measurable

Description: Blood samples were collected for pharmacokinetic analysis of Belrestotug. PK parameters were only calculated for treatment cycles in which sufficient data were available to do so.

Time Frame: Up to 21 days (Cycle 1)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: ug/mL

Percentage:

Arm Reporting Groups								
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD		**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**	
Number of subjects that started the Arm:	10		7		11		10	
Number of Subjects Analyzed:	10		7		11		10	
Comment: (The comment is mandatory when the number of subjects analysed is zero)								
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Cmax	126.386	21.8676	137.837	34.5390	153.377	33.5154	22.967	7.0701
Cmin	19.408	6.4103	20.752	11.5836	153.069	54.3450	21.693	9.2699

Secondary: Part 1: Cmax and Cmin of Dostarlimab (Arm 4) - PK population

Countable or measurable? Measurable

Description: Blood samples were collected for pharmacokinetic analysis of Dostarlimab. PK parameters were only calculated for treatment cycles in which sufficient data were available to do so.

Time Frame: Up to 21 days (Cycle 1)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: ug/mL

Percentage:

Arm Reporting Groups						
	Overall Study Arm 4: Dostarlimab + Belrestotug [low dose (LD)]		**Overall Study Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**		**Overall Study Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**	
Number of subjects that started the Arm:	6		9		9	
Number of Subjects Analyzed:	6		9		9	
Comment: (The comment is mandatory when the number of subjects analysed is zero)						
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Cmax	119.400	60.9173	124.278	40.6026	97.433	34.2035
Cmin	33.900	15.3454	34.071	8.5638	22.935	7.9792

Secondary: Part 1: Cmax and Cmin of Dostarlimab (Arm 5) - PK population

Countable or measurable?	Measurable
Description:	Blood samples were collected for pharmacokinetic analysis of Dostarlimab. PK parameters were only calculated for treatment cycles in which sufficient data were available to do so.
Time Frame:	Up to 21 days (Cycle 1)
Measure Type:	Arithmetic Mean
Precision/Dispersion Type:	Standard Deviation
Units:	ug/mL
Percentage:	

Arm Reporting Groups								
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD		**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**		**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**	
Number of subjects that started the Arm:	10		7		11		10	
Number of Subjects Analyzed:	10		7		11		10	
Comment: (The comment is mandatory when the number of subjects analysed is zero)								
	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Cmax	108.920	32.2323	126.857	51.0830	68.751	43.8090	109.330	121.1920

Cmin	29.290	12.4519	34.550	13.2960	34.218	12.3900	39.013	26.8319

Secondary: Part 1: Cmax and Cmin of Nelistotug (Arm 5) - PK population

Countable or measurable? Measurable

Description: Blood samples were collected for pharmacokinetic analysis of Nelistotug. PK parameters were only calculated for treatment cycles in which sufficient data were available to do so.

Time Frame: Up to 21 days (Cycle 1)

Measure Type: Arithmetic Mean

Precision/Dispersion Type: Standard Deviation

Units: ug/mL

Percentage:

Arm Reporting Groups				
	Overall Study Arm 5 Safety Part: BelrestotugMD + Dostarlimab + NelistotugMD	**Overall Study Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD**	**Overall Study Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugHD**
Number of subjects that started the Arm:	10	7	11	10
Number of Subjects Analyzed:	10	7	11	10
Comment: (The comment is mandatory when the number of subjects analysed is zero)				

	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation	Arithmetic Mean	Standard Deviation
Cmax	299.889	313.2561	479.714	219.7148	75.580	12.4318	554.750	140.7792
Cmin	43.689	13.7240	88.243	34.7201	15.070	2.9601	123.975	66.4588

Secondary: Part 2: Survival rate at 12 and 18 months

Countable or measurable? Measurable

Description: Survival rate was planned to be anaysed at 12 and 18 months. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: At 12 and 18 months

Measure Type: Median

Precision/Dispersion Type: Full Range (min-max)

Units: Months

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Number of participants with Complete response (CR), Partial response (PR), Stable disease (SD) and Progressive disease (PD)

Countable or measurable? Countable

Description: CR, PR, SD and PD was planned to be evaluated as per RECIST version 1.1 criteria. CR was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 mm in the short axis. PR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease. PD was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as a reference, the smallest sum of diameters recorded since the treatment started (e.g. percent change from nadir, where nadir is defined as the smallest sum of diameters recorded since treatment start). In addition, the sum must have an absolute increase from nadir of 5mm. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Progression-free survival (PFS)

Countable or measurable? Countable

Description: PFS is defined as time from the date of randomization to the date of disease progression as per RECIST v1.1. or death whichever occurs earlier. Progressive Disease was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as a reference, the smallest sum of diameters recorded since the treatment started (e.g. percent change from nadir, where nadir is defined as the smallest sum of diameters recorded since treatment start). In addition, the sum must have an absolute increase from nadir of 5mm. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Months

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Objective response rate (ORR)

Countable or measurable? Countable

Description: ORR was defined as the percentage of participants with a best overall confirmed Complete response (CR) or Partial response (PR) at any time as per disease-specific criteria per RECIST version 1.1. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Percentage of participant

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Duration of response (DOR)

Countable or measurable? Measurable

Description: DOR is defined as the time for first documented evidence of CR or PR until disease progression or death, per RECIST 1.1 criteria. Complete Response (CR) was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. Partial Response (PR) was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Measure Type: Median

Precision/Dispersion Type: Inter-Quartile Range (Q1-Q3)

Units: Months

Percentage:

Arm Reporting Groups

Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Disease control rate (DCR)

Countable or measurable? Countable

Description: DCR is defined as the percentage of participants with a confirmed CR + PR at any time, plus SD =>12 weeks as per RECIST v1.1. CR was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. PR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). SD was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Percentage of participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Number of participants with immune-based (i) complete response (iCR), partial response (iPR), unconfirmed progressive disease (iUPD), confirmed progressive disease (iCPD), and stable disease (iSD)

Countable or measurable? Countable

Description: Modified RECIST 1.1 for immune-based therapeutics (iRECIST) is based on RECIST v 1.1 but adapted to account for the unique tumor response seen with immunotherapeutic drugs. iRECIST was used to assess tumor response and progression and make treatment decisions. iCR: disappearance of all target lesions; iPR: at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters (e.g. percent change from baseline). iCPD: either 20% increase in the sum of the longest diameter of target lesions, or a measurable increase in a non-target lesion, or the appearance of new lesions; iSD: stable disease in the absence of CR or PD and iUPD: unconfirmed progressive disease when PD is unconfirmed and NE: not evaluable. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Progression-free survival (iPFS)

Countable or measurable? Countable

Description: iPFS is defined as time from the date of randomization to the date of disease progression or death, whichever occurs earlier, per iRECIST criteria. Progressive Disease was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as a reference, the smallest sum of diameters recorded since the treatment started (e.g. percent change from nadir, where nadir is defined as the smallest sum of diameters recorded since treatment start). In addition, the sum must have an absolute increase from nadir of 5mm. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Months

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Objective response rate (iORR)

Countable or measurable? Countable

Description: iORR is defined as the percentage of participants with a confirmed iCR or iPR at any time per iRECIST criteria. iCR was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Percentage of participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Duration of response (iDOR)

Countable or measurable?	Measurable
Description:	iDOR is defined as the time from first documented evidence of CR or PR until disease progression or death, per iRECIST criteria. iCR was defined as disappearance of all target and non target lesions and any pathological lymph nodes must be <10 millimeter (mm) in the short axis. iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters. No participants were enrolled in Part 2 of the study. Hence, data was not collected.
Time Frame:	Up to 107 weeks
Measure Type:	Median
Precision/Dispersion Type:	Full Range (min-max)
Units:	Months

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:

Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Number of participants with AEs, SAEs, adverse events of special interest (AESI), AE/SAEs leading to dose modifications/delays/withdrawals

Countable or measurable? Countable

Description: An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study intervention, whether or not considered related to the study intervention. An SAE was defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, is a congenital anomaly/birth defect, any other situation such as important medical events according to medical or scientific judgement. AESI are considered to be Infusion Related Reactions (IRRs) and those of potential immunologic etiology. AEs were planned to be coded using the MedDRA coding system. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Number of participants with clinically significant changes in vital signs and laboratory parameters

Countable or measurable?	Countable
Description:	Blood samples were planned to be collected for the analysis of laboratory parameters and vital signs. No participants were enrolled in Part 2 of the study. Hence, data was not collected.
Time Frame:	Up to 107 weeks
Units:	Participants
Percentage:	

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Cmax and Cmin for Dostarlimab

Countable or measurable?	Measurable

Description:	Blood samples were planned to be collected to investigate the pharmacokinetics of Dostarlimab. No participants were enrolled in Part 2 of the study. Hence, data was not collected.
Time Frame:	Up to 107 weeks
Measure Type:	Geometric Mean
Precision/Dispersion Type:	Geometric Coefficient of Variation
Units:	ug/mL
Percentage:	

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Cmax and Cmin for Belrestotug

Countable or measurable?	Measurable
Description:	Blood samples were planned to be collected to investigate the pharmacokinetics of Belrestotug. No participants were enrolled in Part 2 of the study. Hence, data was not collected.
Time Frame:	Up to 107 weeks
Measure Type:	Geometric Mean
Precision/Dispersion Type:	Geometric Coefficient of Variation

Units: ug/mL

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Secondary: Part 2: Number of participants with positive anti-drug antibodies (ADA)

Countable or measurable? Countable

Description: Serum samples were planned to be collected for the analysis of the presence of ADAs using validated immunoassays. No participants were enrolled in Part 2 of the study. Hence, data was not collected.

Time Frame: Up to 107 weeks

Units: Participants

Percentage:

Arm Reporting Groups
Number of subjects that started the Arm:
Number of Subjects Analyzed:
Comment: (The comment is mandatory when the number of subjects analysed is zero)

Adverse Events

Adverse Events

Adverse Events Information

Timeframe for adverse event reporting

All cause mortality, non-SAEs and SAEs were collected up to approximately 97 weeks for arm 4 and up to approximately 107 weeks for arm 5.

Adverse events reporting additional description

Safety Population included all participants who received at least 1 dose of standard of care (SoC) or experimental regimen based on actual treatment received.

Assessment Type	Systematic
Frequency threshold for reporting non-serious adverse events:	5
Dictionary name	MedDRA
Dictionary name - if other	
Dictionary version	27.0

Adverse Events Reporting Groups

Reporting Group Totals	**Arm 4: Dostarlimab + Belrestotug [low dose (LD)]** Participants with Non-small Cell Lung Cancer (NSCLC) received 500 milligram (mg) dostarlimab followed by low dose of GSK4428859A, both via intravenous (IV) infusion from day 1 to once every 3 weeks (Q3W) for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	**Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]** Participants with NSCLC received 500 mg dostarlimab followed by medium dose of GSK4428859A, both via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	**Arm 4: Dostarlimab + Belrestotug [high dose (HD)]** Participants with NSCLC received 500 mg dostarlimab followed by high dose of GSK4428859A, both via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	**Arm5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugMD** Participants with NSCLC received 500 mg dostarlimab followed by medium dose of GSK4428859A followed by low dose of GSK6097608. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.
Total # Subjects Exposed	6	9	9	10
Total # Subjects Affected by Serious Adverse Events	0	3	2	3
Total # Subjects Affected by Non Serious Adverse Events	6	9	8	10
Total # of Deaths (all causes)	4	5	7	7
Total # of Deaths Resulting From Adverse Events				

Reporting Group Totals	**Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD** Participants with NSCLC received 500 mg dostarlimab followed by medium dose of GSK4428859A followed by medium dose of GSK6097608. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	**Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD** Participants with NSCLC received 500 mg dostarlimab followed by medium dose of GSK4428859A followed by high dose of GSK6097608. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.	**Arm5RandomizedPart: BelrestotugMD + Dostarlimab +NelistotugHD** Participants with NSCLC received 500 mg dostarlimab followed by medium dose of GSK4428859A followed by medium dose of GSK6097608. Treatment were given via IV infusion from day 1 to Q3W for maximum duration of approximately 2 years or up to 35 treatment visits whichever comes first, or until disease progression, death, unacceptable toxicity, or other protocol-defined criteria are met.
Total # Subjects Exposed	7	11	10
Total # Subjects Affected by Serious Adverse Events	3	3	3
Total # Subjects Affected by Non Serious Adverse Events	6	11	9
Total # of Deaths (all causes)	4	7	6
Total # of Deaths Resulting From Adverse Events			

Serious Adverse Events

Reporting Groups	**Arm 4: Dostarlimab + Belrestotug [low dose (LD)]**	**Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]**	**Arm 4: Dostarlimab + Belrestotug [high dose (HD)]**	**Arm5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugMD**	↴

Blood and lymphatic system disorders					
Febrile neutropenia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Cardiac disorders					
Immune-mediated myocarditis					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴
# of occurrences causally related to treatment	0	1	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Gastrointestinal disorders					
Constipation					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	0	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Dysphagia					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	0	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Strangulated umbilical hernia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Infections and infestations					
COVID-19 pneumonia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Pneumonia					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Pneumonia staphylococcal					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Respiratory tract infection					
# of subjects affected	0	0	0	0	↴

# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	0	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Sepsis					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	0	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Injury, poisoning and procedural complications					
Infusion related reaction					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Investigations					
N-terminal prohormone brain natriuretic peptide increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Metabolism and nutrition disorders					
Hyperglycaemia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Cancer pain					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Nervous system disorders					
Epilepsy					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Haemorrhage intracranial					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Ischaemic stroke					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴

# of fatalities causally related to treatment	0	0	0	0	↴

Renal and urinary disorders					
Nephrolithiasis					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴
# of fatalities causally related to treatment	0	0	0	0	↴

Respiratory, thoracic and mediastinal disorders					
Lung disorder					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴
# of occurrences causally related to treatment	0	0	0	0	↴
# of fatalities	0	0	0	0	↴

# of fatalities causally related to treatment	0	0	0	0	↵

Pleural effusion					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	0	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Respiratory failure					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
# of occurrences causally related to treatment	0	0	0	0	↵
# of fatalities	0	0	0	1	↵
# of fatalities causally related to treatment	0	0	0	0	↵

Reporting Groups	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab +NelistotugHD
Blood and lymphatic system disorders			
Febrile neutropenia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Cardiac disorders			
Immune-mediated myocarditis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Gastrointestinal disorders			
Constipation			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Dysphagia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Strangulated umbilical hernia

# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Infections and infestations			
COVID-19 pneumonia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Pneumonia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Pneumonia staphylococcal			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Respiratory tract infection			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Sepsis			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	2	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	1	0
# of fatalities causally related to treatment	0	0	0

Injury, poisoning and procedural complications			
Infusion related reaction			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1
# of occurrences causally related to treatment	0	0	1
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Investigations
N-terminal prohormone brain natriuretic peptide increased

# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Metabolism and nutrition disorders			
Hyperglycaemia			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
# of subjects affected	0	0	0

# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Nervous system disorders			
Epilepsy			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Haemorrhage intracranial			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Ischaemic stroke			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Renal and urinary disorders			
Nephrolithiasis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0

# of fatalities causally related to treatment	0	0	0

Respiratory, thoracic and mediastinal disorders			
Lung disorder			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0
# of occurrences causally related to treatment	0	1	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Pleural effusion			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Respiratory failure			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
# of occurrences causally related to treatment	0	0	0
# of fatalities	0	0	0
# of fatalities causally related to treatment	0	0	0

Non Serious Adverse Events

Threshold for non-serious adverse event reporting is: 5%

Reporting Groups	Arm 4: Dostarlimab + Belrestotug [low dose (LD)]	Arm 4: Dostarlimab + Belrestotug [medium dose (MD)]	Arm 4: Dostarlimab + Belrestotug [high dose (HD)]	Arm5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugMD	↴
Blood and lymphatic system disorders					
Anaemia					
# of subjects affected	0	1	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	1	↴

Leukocytosis					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Lymph node pain					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Lymphopenia					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Subcapsular splenic haematoma					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Cardiac disorders					
Pericardial effusion					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
Sinus bradycardia					
# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	0	0	0	↵
Sinus tachycardia					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
Tachycardia					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Endocrine disorders					
Hypophysitis					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Hypothyroidism					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Gastrointestinal disorders					
Abdominal discomfort					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	2	0	0	0	↴

Abdominal pain					
# of subjects affected	1	0	0	1	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	1	↴

Colitis					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Constipation					
# of subjects affected	1	1	0	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	1	0	2	↴

Diarrhoea					
# of subjects affected	0	1	2	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	4	0	↴

Dry mouth					
# of subjects affected	0	0	0	0	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Dyspepsia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Dysphagia					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Gastrooesophageal reflux disease					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Haemorrhoids					
# of subjects affected	0	0	0	0	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Nausea					
# of subjects affected	1	0	2	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	2	2	↴

Swollen tongue					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Tongue ulceration					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Vomiting					
# of subjects affected	2	0	0	1	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	2	0	0	1	↴

General disorders and administration site conditions					
Asthenia					
# of subjects affected	0	2	2	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	2	0	↴
Chest pain					
# of subjects affected	0	1	0	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	2	↴
Chills					
# of subjects affected	0	1	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	1	↴
Discomfort					

# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	2	0	0	0	↵

Face oedema					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵

Fatigue					
# of subjects affected	0	1	1	2	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	1	2	↵

Influenza like illness					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Oedema

# of subjects affected	0	2	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	1	0	↴

Oedema peripheral					
# of subjects affected	0	3	1	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	3	1	1	↴

Pain					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Peripheral swelling					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Pyrexia

# of subjects affected	1	2	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	2	1	0	↴

Xerosis					
# of subjects affected	0	2	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	0	0	↴

Immune system disorders					
Contrast media allergy					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Drug hypersensitivity					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Infections and infestations

Candida infection					
# of subjects affected	0	1	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	1	↵

Cellulitis					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

COVID-19					
# of subjects affected	0	0	2	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	2	1	↵

Gastroenteritis viral					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵

Herpes zoster					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Infection					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Lower respiratory tract infection					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵

Nasopharyngitis					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Pneumonia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Rash pustular					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Respiratory tract infection					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Upper respiratory tract infection					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Varicella zoster virus infection					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Injury, poisoning and procedural complications					
Hand fracture					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Infusion related reaction					
# of subjects affected	1	1	3	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	2	1	3	0	↴

Procedural pain					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Scratch					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Spinal fracture					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Investigations					
Alanine aminotransferase increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Amylase increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴

# of occurrences (all)	0	0	0	0	↴

Aspartate aminotransferase increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Blood bilirubin increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Blood creatinine increased					
# of subjects affected	0	0	1	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	2	↴

Blood potassium decreased					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴

# of occurrences (all)	0	0	1	0	↴

Blood sodium increased					
# of subjects affected	0	0	0	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	2	↴

Brain natriuretic peptide increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Breath sounds abnormal					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

C-reactive protein increased					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴

# of occurrences (all)	0	0	0	1	↴

Haemoglobin decreased					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Lipase increased					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Neutrophil count increased					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

N-terminal prohormone brain natriuretic peptide increased					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴

# of occurrences (all)	0	0	0	1	↴

Troponin increased					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	0	0	↴

Troponin T increased					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Weight decreased					
# of subjects affected	1	1	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	1	1	0	↴

Metabolism and nutrition disorders					
Decreased appetite					
# of subjects affected	2	4	1	1	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	2	4	1	1	↴

Dehydration					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Fluid retention					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Hypercalcaemia					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Hypoalbuminaemia					
# of subjects affected	0	1	0	0	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Hypokalaemia					
# of subjects affected	0	1	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	1	0	↴

Hyponatraemia					
# of subjects affected	0	2	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	0	1	↴

Hypophosphataemia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Musculoskeletal and connective tissue disorders
Arthralgia

# of subjects affected	1	2	0	2	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	3	0	3	↵

Arthritis					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵

Back pain					
# of subjects affected	1	1	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	1	1	0	↵

Coccydynia					
# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	0	0	0	↵

Groin pain

# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	0	0	0	↵

Limb discomfort					
# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	0	0	0	↵

Muscle spasms					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵

Muscular weakness					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵

Musculoskeletal chest pain

# of subjects affected	0	2	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	2	0	1	↵

Myalgia					
# of subjects affected	1	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	0	0	0	↵

Pain in extremity					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Pain in jaw					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Sacral pain

# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Spinal pain					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Metastases to bone					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Nervous system disorders					
Balance disorder					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Cognitive disorder					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Cranial nerve disorder					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Dizziness					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Dysaesthesia					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Dysarthria					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Dysgeusia					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Headache					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Memory impairment					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Migraine					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Neuralgia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Neuropathy peripheral					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Paraesthesia					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Sensory loss					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Somnolence					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Psychiatric disorders					
Abnormal dreams					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Anxiety					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴

Confusional state					
# of subjects affected	0	2	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	0	0	↴

Depression					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Hallucination					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Insomnia					
# of subjects affected	1	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	1	↴

Renal and urinary disorders					
Azotaemia					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
Hydronephrosis					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵
Nephritis					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵
Pollakiuria					
# of subjects affected	0	1	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	0	0	↵

Renal failure					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴

Reproductive system and breast disorders					
Gynaecomastia					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴

Respiratory, thoracic and mediastinal disorders					
Bronchial fistula					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Bronchial obstruction					
# of subjects affected	0	0	0	0	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Chronic obstructive pulmonary disease					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Cough					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Dysphonia					
# of subjects affected	0	1	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	1	↴

Dyspnoea					
# of subjects affected	0	2	0	0	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	2	0	0	↴

Dyspnoea exertional					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Epistaxis					
# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Haemoptysis					
# of subjects affected	1	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	1	0	0	↴

Hypoxia					
# of subjects affected	0	0	0	1	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Immune-mediated lung disease					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Nasal congestion					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴

Oropharyngeal pain					
# of subjects affected	1	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	1	0	0	0	↴

Pleural effusion					
# of subjects affected	0	0	0	1	↴

# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Pleuritic pain					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Pneumonitis					
# of subjects affected	0	0	0	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	2	↴

Productive cough					
# of subjects affected	0	0	1	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	1	0	↴

Rhinitis allergic					
# of subjects affected	0	0	0	0	↴

# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Skin and subcutaneous tissue disorders					
Capillaritis					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵

Dermatitis acneiform					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Dermatitis psoriasiform					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Dry skin

# of subjects affected	0	1	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	1	1	0	↵

Eczema

# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵

Erythema

# of subjects affected	1	1	0	2	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	1	1	0	2	↵

Night sweats

# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Petechiae

# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Pruritus					
# of subjects affected	2	3	2	2	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	4	3	2	3	↵

Psoriasis					
# of subjects affected	0	0	0	1	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	1	↵

Rash					
# of subjects affected	2	1	1	2	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	2	1	1	3	↵

Rash erythematous

# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Rash macular

# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Rash papular

# of subjects affected	0	0	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	0	↴

Rash pruritic

# of subjects affected	1	0	1	2	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	3	0	1	2	↴

Rash vesicular

# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Skin disorder					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Skin lesion					
# of subjects affected	0	0	1	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	1	0	↵

Skin plaque					
# of subjects affected	0	0	0	0	↵
# of subjects exposed	6	9	9	10	↵
# of occurrences (all)	0	0	0	0	↵

Vascular disorders

Hypertension					
# of subjects affected	0	0	0	1	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	0	0	1	↴

Hypotension					
# of subjects affected	0	1	0	0	↴
# of subjects exposed	6	9	9	10	↴
# of occurrences (all)	0	1	0	0	↴

Reporting Groups	Arm 5 SafetyPart: BelrestotugMD + Dostarlimab + NelistotugHD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab + NelistotugLD	Arm5RandomizedPart: BelrestotugMD + Dostarlimab +NelistotugHD
Blood and lymphatic system disorders			
Anaemia			
# of subjects affected	2	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	2	0	1

Leukocytosis

# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Lymph node pain			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Lymphopenia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Subcapsular splenic haematoma			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Cardiac disorders

Pericardial effusion			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Sinus bradycardia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Sinus tachycardia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Tachycardia			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Endocrine disorders			
Hypophysitis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hypothyroidism			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Gastrointestinal disorders			
Abdominal discomfort			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Abdominal pain			
# of subjects affected	0	1	2
# of subjects exposed	7	11	10

# of occurrences (all)	0	1	2

Colitis			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Constipation			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Diarrhoea			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Dry mouth			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10

# of occurrences (all)	0	0	1

Dyspepsia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Dysphagia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Gastrooesophageal reflux disease			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Haemorrhoids			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10

# of occurrences (all)	1	0	0

Nausea			
# of subjects affected	0	3	2
# of subjects exposed	7	11	10
# of occurrences (all)	0	3	2

Swollen tongue			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Tongue ulceration			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	2	0	0

Vomiting			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10

# of occurrences (all)	0	1	0

General disorders and administration site conditions			
Asthenia			
# of subjects affected	0	3	2
# of subjects exposed	7	11	10
# of occurrences (all)	0	3	2

Chest pain			
# of subjects affected	0	1	3
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	3

Chills			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Discomfort			
# of subjects affected	0	0	0

# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Face oedema			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Fatigue			
# of subjects affected	1	3	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	3	0

Influenza like illness			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Oedema			
# of subjects affected	0	0	0

# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Oedema peripheral			
# of subjects affected	0	2	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	2	1

Pain			
# of subjects affected	1	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	1

Peripheral swelling			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Pyrexia			
# of subjects affected	2	0	0

# of subjects exposed	7	11	10
# of occurrences (all)	2	0	0

Xerosis			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Immune system disorders			
Contrast media allergy			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Drug hypersensitivity			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Infections and infestations			
Candida infection			

# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Cellulitis			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

COVID-19			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	10	0	0

Gastroenteritis viral			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Herpes zoster

# of subjects affected	1	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	2	0	1

Infection			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Lower respiratory tract infection			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Nasopharyngitis			
# of subjects affected	1	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	2	0

Pneumonia

# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Rash pustular			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Respiratory tract infection			
# of subjects affected	1	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	1

Upper respiratory tract infection			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Varicella zoster virus infection

# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Injury, poisoning and procedural complications			
Hand fracture			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Infusion related reaction			
# of subjects affected	3	5	1
# of subjects exposed	7	11	10
# of occurrences (all)	3	5	1

Procedural pain			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Scratch			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Spinal fracture			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Amylase increased			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Aspartate aminotransferase increased			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Blood bilirubin increased			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Blood creatinine increased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Blood potassium decreased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Blood sodium increased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Brain natriuretic peptide increased			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Breath sounds abnormal			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

C-reactive protein increased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Haemoglobin decreased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Lipase increased			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Neutrophil count increased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

N-terminal prohormone brain natriuretic peptide increased			
# of subjects affected	0	2	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	2	0

Troponin increased			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Troponin T increased			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Weight decreased			
# of subjects affected	2	2	1
# of subjects exposed	7	11	10
# of occurrences (all)	2	2	1

Metabolism and nutrition disorders			
Decreased appetite			
# of subjects affected	1	2	2
# of subjects exposed	7	11	10
# of occurrences (all)	1	3	2

Dehydration			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Fluid retention			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hypercalcaemia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hypoalbuminaemia			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	2

Hypokalaemia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hyponatraemia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Hypophosphataemia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	5	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
# of subjects affected	0	1	2
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	2

Arthritis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Back pain			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	2	0	0

Coccydynia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Groin pain			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Limb discomfort			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Muscle spasms			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Muscular weakness			
# of subjects affected	1	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	1	0

Musculoskeletal chest pain			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Myalgia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Pain in extremity			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Pain in jaw			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Sacral pain			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Spinal pain			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to bone			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Nervous system disorders			
Balance disorder			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Cognitive disorder			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10

# of occurrences (all)	0	1	0

Cranial nerve disorder			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Dizziness			
# of subjects affected	0	2	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	2	0

Dysaesthesia			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Dysarthria			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10

# of occurrences (all)	0	1	0

Dysgeusia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Headache			
# of subjects affected	1	2	1
# of subjects exposed	7	11	10
# of occurrences (all)	1	2	1

Memory impairment			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Migraine			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10

# of occurrences (all)	0	1	0

Neuralgia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Neuropathy peripheral			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Paraesthesia			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Sensory loss			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10

# of occurrences (all)	0	0	0

Somnolence			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Psychiatric disorders			
Abnormal dreams			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Anxiety			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Confusional state			
# of subjects affected	0	1	0

# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Depression			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hallucination			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Insomnia			
# of subjects affected	0	1	2
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	2

Renal and urinary disorders
Azotaemia

# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hydronephrosis			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Nephritis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Pollakiuria			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Renal failure

# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Reproductive system and breast disorders			
Gynaecomastia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Bronchial fistula			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Bronchial obstruction			
# of subjects affected	1	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	0	0

Chronic obstructive pulmonary disease			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Cough			
# of subjects affected	1	1	2
# of subjects exposed	7	11	10
# of occurrences (all)	1	1	2

Dysphonia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Dyspnoea			
# of subjects affected	0	2	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	2	1

Dyspnoea exertional			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Epistaxis			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Haemoptysis			
# of subjects affected	1	2	0
# of subjects exposed	7	11	10
# of occurrences (all)	1	2	0

Hypoxia			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Immune-mediated lung disease			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Nasal congestion			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Oropharyngeal pain			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Pleural effusion			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Pleuritic pain			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Pneumonitis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Productive cough			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Rhinitis allergic			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Skin and subcutaneous tissue disorders			
Capillaritis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
Dermatitis acneiform			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
Dermatitis psoriasiform			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0
Dry skin			
# of subjects affected	1	1	1
# of subjects exposed	7	11	10
# of occurrences (all)	1	1	1

Eczema			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Erythema			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Night sweats			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Petechiae			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Pruritus			
# of subjects affected	1	2	3
# of subjects exposed	7	11	10
# of occurrences (all)	2	3	5

Psoriasis			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Rash			
# of subjects affected	2	1	1
# of subjects exposed	7	11	10
# of occurrences (all)	2	1	1

Rash erythematous			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

Rash macular			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Rash papular			
# of subjects affected	1	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	2	1	0

Rash pruritic			
# of subjects affected	2	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	2	0	0

Rash vesicular			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Skin disorder			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Skin lesion			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Skin plaque			
# of subjects affected	0	0	1
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	1

Vascular disorders			
Hypertension			
# of subjects affected	0	0	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	0	0

Hypotension			
# of subjects affected	0	1	0
# of subjects exposed	7	11	10
# of occurrences (all)	0	1	0

More Information

More Information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Amendment Date	Description
20-Sep-2018	Protocol was amended at the request of the regulatory authority to provide additional clarification and guidance on specific aspects of the protocol
15-Jul-2019	Protocol was amended based on regulatory and ethics committee feedback to provide additional clarification and guidance on specific aspects of the protocol
29-Oct-2020	The protocol has been amended to introduce three new substudies into Section 12.1.3, Section 12.1.4, and Section 12.1.5 of the protocol.
02-Feb-2021	The protocol has been amended to clarify substudies included in previous amendment and to align with updates to study strategy
02-Sep-2021	The protocol has been amended to introduce a new arm under Section 12.1 (subsection 12.1.4). In addition, changes were made in line with study design
19-Nov-2021	The protocol has been amended to introduce a new arm under Section 12.1 (subSection 12.1.5). In addition, changes were made in line with study design
08-Mar-2022	The protocol has been amended to include additional safety assessments for cardiac monitoring in the Schedule of Activities under Section 12.1 (subsection 12.1.4 and 12.1.5).

Amendment Date	Description
23-May-2022	The protocol has been amended to include additional safety assessments for cardiac monitoring in the Schedule of Activities under Section 12.1 (sub Section 12.1.4 and Section 12.1.5).
30-Mar-2023	Amendment 09 provides additional cardiac risk mitigation measures, including updated requirements for mandatory cardiology or locally appropriate specialist consultation in the event of specified cardiac indicators.
26-Apr-2023	Amendment 10 provides updated eligibility requirements with regards to toxicity from previous immunotherapy treatment.

Interruptions (globally)

For any interruption, the restart date must not be before the interruption date.

Were there any global interruptions to the trial? No

Interruption Date	Description	Restart Date

Limitations and caveats

Limitations and caveats applicable to this summary of the results

Online References

Provide identifiers to retrieve publications of interest in regards to the results of this clinical trial.

Enter PubMed Identifier (PMID)