Study Results

Participant Flow

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Overall Study

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Started	35	70
Completed	0	0
Not Completed	35	70
Death	25	62
Site Closed	6	6
Lost to Follow-up	1	0
Withdrawal by Subject	3	2

Baseline Characteristics

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Baseline Measures

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total
Overall Number of Participants		35	70	105
Age, Continuous	Mean (Standard Deviation) Unit of measure: years Number Analyzed	35 participants	70 participants	105 participants
		62.6 (10.48)	64.4 (9.11)	63.8 (9.57)
Age, Customized	Measure Type: Count of Participants Unit of measure: participants Number Analyzed	35 participants	70 participants	105 participants
18-64		22 62.86%	31 44.29%	53 50.48%
65-74		7 20%	28 40%	35 33.33%
75-84		5 14.29%	11 15.71%	16 15.24%
>=85		1 2.86%	0 0%	1 0.95%
Sex: Female, Male	Measure Type: Count of Participants Unit of measure: participants Number Analyzed	35 participants	70 participants	105 participants
	Female	8 22.86%	17 24.29%	25 23.81%
	Male	27 77.14%	53 75.71%	80 76.19%
Ethnicity	Measure Type: Count of Participants	35 participants	70 participants	105 participants

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total
(NIH/OMB)	Unit of measure: participants Number Analyzed			
	Hispanic or Latino	0 0%	2 2.86%	2 1.9%
	Not Hispanic or Latino	35 100%	67 95.71%	102 97.14%
	Unknown or Not Reported	0 0%	1 1.43%	1 0.95%
Region of Enrollment	Measure Type: Number Unit of measure: participants Number Analyzed	35 participants	70 participants	105 participants
Canada		3	0	3
South Korea		4	5	9
Netherlands		0	3	3
Sweden		0	2	2
Romania		2	9	11
United States		5	7	12
Poland		1	3	4
Italy		4	7	11
France		6	9	15
Germany		3	7	10

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total
Spain		4	13	17
Russia		3	5	8

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Overall survival was calculated as time from randomization to death. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Up to 2 years

Analysis Population Description

Intent To Treat population (ITT) included all participants who were randomized to treatment regardless of whether the participants actually received study treatment.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
Overall Survival	Median (95% Confidence Interval) Unit of measure: Months 8.2 (4.5 to 16.1)	7.8 (4.7 to 10.8)

2. Secondary Outcome Measure:

Measure Title	Kaplan-Meier Estimates of Overall Survival at 12 and 18 Months
Measure Description	Overall survival was defined as the time between date of randomization and death due to any cause. Kaplan-Meier estimates of the percentage of participants who died at each time point was calculated. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Month 12 and 18

Analysis Population Description
Intent-To-Treat Population.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
Kaplan-Meier Estimates of Overall Survival at 12 and 18 Months	Number (95% Confidence Interval) Unit of measure: Percentage of Participants	
Month 12	44 (27 to 60)	28 (18 to 39)
Month 18	28 (14 to 44)	18 (10 to 28)

3. Secondary Outcome Measure:

Measure Title	Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD) or Not Evaluable
Measure Description	CR, PR, SD and PD will be evaluated as per RECIST version 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 (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. 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.
Time Frame	Up to 2 years

Analysis Population Description
Intent-To-Treat Population.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD) or Not Evaluable	Measure Type: Count of Participants Unit of measure: participants	
Complete Response	0 0%	0 0%
Partial Response	4 11.43%	13 18.57%
Stable Disease	10 28.57%	22 31.43%
Progressive Disease	14 40%	23 32.86%
Not Evaluable	7 20%	12 17.14%

4. Secondary Outcome Measure:

Measure Title	Kaplan-Meier Estimates of Progression-Free Survival (PFS)
Measure 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. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Up to 2 years

Analysis Population Description

Intent to Treat Population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m2	Participants with NSLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion once Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2
Overall Number of Participants Analyzed	29	62
Kaplan-Meier Estimates of Progression-Free Survival (PFS)	Median (95% Confidence Interval) Unit of measure: Months 3.3 (1.6 to 4.2)	3.4 (2.6 to 4.3)

5. Secondary Outcome Measure:

Measure Title	Objective Response Rate
Measure Description	ORR was calculated as the percentage of participants with a confirmed complete response (CR) or partial response (PR) relative to the total number of participants in the analysis population per response evaluation criteria in solid tumors (RECIST) version (v)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.
Time Frame	Up to 2 years

Analysis Population Description

Intent-To-Treat Population

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2
Overall Number of Participants Analyzed	35	70
Objective Response Rate	Number (95% Confidence Interval) Unit of measure: Percentage of Participants 11 (3.2 to 26.7)	19 (10.3 to 29.7)

6. Secondary Outcome Measure:

Measure Title	Kaplan-Meier Estimates of Duration of Response (DOR) in Participants With Objective Response
Measure 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. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Up to 2 years

Analysis Population Description

Intent To Treat Population. Only participants who achieved Objective Response were evaluated.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	4	13
Kaplan-Meier Estimates of Duration of Response (DOR) in Participants With Objective Response	Median (95% Confidence Interval) Unit of measure: Months 4.8 (2.8 to NA) [1]	4.3 (2.4 to 8.7)

[1] Upper limit was not calculated due to insufficient number of participants with events.

7. Secondary Outcome Measure:

Measure Title	Disease Control Rate (DCR)
Measure 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 2 years

Analysis Population Description
Intent-to-Treat Population.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
Disease Control Rate (DCR)	Number (95% Confidence Interval) Unit of measure: Percentage of Participants 40 (23.9 to 57.9)	50 (37.8 to 62.2)

8. Secondary Outcome Measure:

Measure Title	Number of Participants With iRECIST Complete Response (iCR), Partial Response (iPR), Unconfirmed Progressive Disease (iUPD), Confirmed Progressive Disease (iCPD), Stable Disease (iSD) or Not Evaluable
Measure 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.
Time Frame	Up to 2 years

Analysis Population Description
Intent-To-Treat Population.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
Number of Participants With iRECIST Complete Response (iCR), Partial Response (iPR), Unconfirmed Progressive Disease (iUPD), Confirmed Progressive Disease (iCPD), Stable Disease (iSD) or Not Evaluable	Measure Type: Count of Participants Unit of measure: participants	
iCR	0 0%	0 0%
iPR	4 11.43%	13 18.57%
iUPD	11 31.43%	15 21.43%

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
iCPD	3 8.57%	8 11.43%
iSD	10 28.57%	22 31.43%
Not Evaluable	7 20%	12 17.14%

9. Secondary Outcome Measure:

Measure Title	Kaplan-Meier Estimates of iRECIST Progression-free Survival (iPFS)
Measure 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. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Up to 2 years

Analysis Population Description

Intent-to-Treat population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2
Overall Number of Participants Analyzed	29	62
Kaplan-Meier Estimates of iRECIST Progression-free Survival (iPFS)	Median (95% Confidence Interval) Unit of measure: Months 3.3 (1.6 to 4.2)	3.4 (2.6 to 4.3)

10. Secondary Outcome Measure:

Measure Title	iRECIST Objective Response Rate (iORR)
Measure 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.
Time Frame	Up to 2 years

Analysis Population Description
Intent-to-Treat population.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	35	70
iRECIST Objective Response Rate (iORR)	Number (95% Confidence Interval) Unit of measure: Percentage of Participants 11 (3.2 to 26.7)	19 (10.3 to 29.7)

11. Secondary Outcome Measure:

Measure Title	Kaplan-Meier Estimates of iRECIST Duration of Response (iDOR) in Participants With Objective Response
Measure 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. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame	Up to 2 years

Analysis Population Description

Intent-To-Treat Population. Only the participants with Objective Response were evaluated.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	4	13
Kaplan-Meier Estimates of iRECIST Duration of Response (iDOR) in Participants With Objective Response	Median (95% Confidence Interval) Unit of measure: Months 4.8 (2.8 to NA) [1]	4.3 (2.4 to 8.7)

[1] Upper limit was not calculated due to insufficient number of participants with events.

12. Secondary Outcome Measure:

Measure Title	Number of Participants With AEs, Adverse Events of Special Interest (AESI), SAEs and AE/SAEs Leading to Dose Modifications/Delays/Withdrawals
Measure 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.
Time Frame	Up to 2 years

Analysis Population Description

Safety Population included all the randomized participants who received at least one dose of Standard of Care (SoC), or experimental regimen based on actual treatment received.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2)

	Description
	monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	34	70
Number of Participants With AEs, Adverse Events of Special Interest (AESI), SAEs and AE/SAEs Leading to Dose Modifications/Delays/Withdrawals	Measure Type: Count of Participants Unit of measure: participants	
AEs	34 100%	70 100%
AESI	1 2.94%	4 5.71%
SAEs	16 47.06%	34 48.57%
AEs leading to permanent discontinuation of study treatment	12 35.29%	16 22.86%
AEs leading to dose reduction	7 20.59%	13 18.57%
AEs leading to dose interruption/delay	11 32.35%	24 34.29%

13. Secondary Outcome Measure:

Measure Title	Number of Participants With Maximum Grade Increase in Clinical Chemistry Parameters at Worst Case Post-Baseline
Measure Description	Blood samples were collected for assessment of the clinical chemistry parameters. Laboratory grades were evaluated using the Common Terminology Criteria for Adverse Events (CTCAE v5.0). Grade 1 = Mild AE; Grade 2 = Moderate AE; Grade 3 = Severe AE; Grade 4 = Life-threatening or disabling AE. Number of participants with clinical chemistry results by maximum grade increase (Increase to Grade 3 or Increase to Grade 4) are presented.
Time Frame	Up to 2 years

Analysis Population Description

Safety Population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed		34	63
Number of Participants With Maximum Grade Increase in Clinical Chemistry Parameters at Worst Case Post-Baseline	Measure Type: Count of Participants Unit of measure: participants [Not specified]		
Blood bilirubin increased	Number Analyzed	34 participants	63 participants
		0 0%	1 1.59%
Hypercalcemia	Number Analyzed	34 participants	61 participants
		0 0%	2 3.28%
Creatinine increased	Number Analyzed	34 participants	63 participants
		0 0%	1 1.59%

14. Secondary Outcome Measure:

Measure Title	Number of Participants With Maximum Grade Increase in Hematology Parameters at Worst Case Post-Baseline
Measure Description	Blood samples were collected for assessment of the hematology parameters. Laboratory grades were evaluated using the Common Terminology Criteria for Adverse Events (CTCAE v5.0). Grade 1 = Mild AE; Grade 2 = Moderate AE; Grade 3 = Severe AE; Grade 4 = Life-threatening or disabling AE. Number of participants with Hematology results by maximum grade increase (Increase to Grade 3 or Increase to Grade 4) are presented.
Time Frame	Up to 2 years

Analysis Population Description

Safety Population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	34	64
Number of Participants With Maximum Grade Increase in Hematology Parameters at Worst Case Post-Baseline	Measure Type: Count of Participants Unit of measure: participants	
Anemia	2 5.88%	5 7.81%
Leukocytosis	0 0%	1 1.56%
White blood cell decreased	5 14.71%	11 17.19%
Lymphocyte count decreased	4 11.76%	12 18.75%
Neutrophil count decreased	4 11.76%	13 20.31%
Platelet count decreased	0 0%	3 4.69%

15. Secondary Outcome Measure:

Measure Title	Number of Participants With Maximum Grade Increase in Vital Signs (Systolic Blood Pressure and Diastolic Blood Pressure) Parameters at Worst Case Post-Baseline
Measure Description	Blood Pressure was measured after 5 minutes of rest and was taken in the same position throughout the study. Laboratory grades were evaluated using the Common Terminology Criteria for Adverse Events (CTCAE v5.0). Grade 1 = Mild AE; Grade 2 = Moderate AE; Grade 3 = Severe AE. Number of participants with vital signs results by maximum grade increase (Increase to Grade 2 or Increase to Grade 3) are presented.

Time Frame	Up to 2 years

Analysis Population Description

Safety Population. Only those participants with data available at specified time points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion once Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	34	63
Number of Participants With Maximum Grade Increase in Vital Signs (Systolic Blood Pressure and Diastolic Blood Pressure) Parameters at Worst Case Post-Baseline	Measure Type: Count of Participants Unit of measure: participants	
Diastolic Blood Pressure	12 35.29%	26 41.27%
Systolic Blood Pressure	16 47.06%	28 44.44%

16. Secondary Outcome Measure:

Measure Title	Number of Participants With Vital Signs (Temperature) Parameter Results at Worst Case Post-Baseline
Measure Description	Body temperature was measured after 5 minutes of rest. Results are presented in the following categories: Decrease to <=35 Degrees Celsius, Change to Normal or No Change and Increase to >=38 Degrees Celsius.
Time Frame	Up to 2 years

Analysis Population Description

Safety Population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2)

	Description
	monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	34	63
Number of Participants With Vital Signs (Temperature) Parameter Results at Worst Case Post-Baseline	Measure Type: Count of Participants Unit of measure: participants	
Decrease to <=35 Degrees Celsius	0 0%	6 9.52%
Change to Normal or No Change	33 97.06%	52 82.54%
Increase to >=38 Degrees Celsius	1 2.94%	5 7.94%

17. Secondary Outcome Measure:

Measure Title	Number of Participants With Vital Signs (Pulse Rate) Parameter Results at Worst Case Post-Baseline
Measure Description	Pulse Rate was measured after 5 minutes of rest. Results are presented in the following categories: Decrease to <50 beats per minute, Change to Normal or No Change and Increase to >120 beats per minute.
Time Frame	Up to 2 years

Analysis Population Description

Safety Population. Only those participants with data available at specified data points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSLC were administered with Docetaxel 75 milligram per metersquare (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks(Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion once Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	34	63
Number of Participants With Vital Signs (Pulse Rate) Parameter Results at Worst Case Post-Baseline	Measure Type: Count of Participants Unit of measure: participants	
Decrease to <50 beats per minute	0 0%	0 0%
Change to Normal or No Change	32 94.12%	55 87.3%
Increase to >120 beats per minute	2 5.88%	8 12.7%

18. Secondary Outcome Measure:

Measure Title	Minimum Observed Concentration (CmIn) of Feladilimab
Measure Description	Blood samples were collected for assessment of the pharmacokinetic parameters.
Time Frame	Week 1

Analysis Population Description

Pharmacokinetic (PK) population will consist of all participants from the ITT Population from whom a blood sample was obtained and analyzed for PK concentration.

Reporting Groups

	Description
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	67
Minimum Observed Concentration (CmIn) of Feladilimab	Geometric Mean (Geometric Coefficient of Variation) Unit of measure: nanogram per millimeter (ng/mL) 6104.6 (91.3%)

19. Secondary Outcome Measure:

Measure Title	Maximum Observed Concentration (Cmax) of Feladilimab
Measure Description	Blood samples were collected for assessment of the pharmacokinetic parameters.
Time Frame	Week 1, Week 13 and Week 25

Analysis Population Description

Pharmacokinetic population. Only those participants with data available at specified time points have been analyzed.

Reporting Groups

	Description
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed		67
Maximum Observed Concentration (Cmax) of Feladilimab	Geometric Mean (Geometric Coefficient of Variation) Unit of measure: nanogram per millimeter (ng/mL) [Not specified]	
Week 1	Number Analyzed	67 participants
		24923.7 (26.7%)
Week 13	Number Analyzed	34 participants
		28715.9 (45.4%)
Week 25	Number Analyzed	15 participants
		32688.4 (27.4%)

20. Secondary Outcome Measure:

Measure Title	Maximum Observed Concentration (Cmax) of Docetaxel

Measure Description	Blood samples were collected for assessment of the pharmacokinetic parameters.
Time Frame	Week 1, Week 4, Week 7, Week 10, Week 13, Week 16, Week 19 and Week 22

Analysis Population Description

Pharmacokinetic Population. Only those participants with data available at specified time points have been analyzed.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed		30	55
Maximum Observed Concentration (Cmax) of Docetaxel	Geometric Mean (Geometric Coefficient of Variation) Unit of measure: nanogram per millimeter (ng/mL) [Not specified]		
Week 1	Number Analyzed	30 participants	55 participants
		1500.9 (133.5%)	1429.9 (138.7%)
Week 4	Number Analyzed	29 participants	54 participants
		1587.1 (128.6%)	1399.7 (99.3%)
Week 7	Number Analyzed	17 participants	46 participants
		846.8 (166.4%)	1036.9 (171.2%)
Week 10	Number Analyzed	15 participants	41 participants
		1262.9 (155.4%)	1248.4 (118.3%)

		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Week 13	Number Analyzed	8 participants	32 participants
		1354.2 (212.1%)	1363.4 (137.8%)
Week 16	Number Analyzed	6 participants	32 participants
		1095.3 (114.3%)	1381.9 (114.0%)
Week 19	Number Analyzed	5 participants	15 participants
		759.0 (74.0%)	1765.7 (95.1%)
Week 22	Number Analyzed	3 participants	10 participants
		535.5 (10.9%)	2430.7 (73.3%)

21. Secondary Outcome Measure:

Measure Title	Number of Participants With Positive Anti-drug Antibodies (ADA) Against Docetaxel
Measure Description	
Time Frame	Up to 2 years

Analysis Population Description

Data was not collected.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

Measured Values

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2

	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

22. Secondary Outcome Measure:

Measure Title	Number of Participants With Positive ADA Against Feladilimab
Measure Description	
Time Frame	Week 1, 4, 7, 10, 13, 16, 19, 22, 25, 37, 49, 61 and 73

Analysis Population Description

Safety population. Only those participants with data available at specified time points have been analyzed.

Reporting Groups

	Description
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSCLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion once Q3W.

Measured Values

		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Overall Number of Participants Analyzed		69
Number of Participants With Positive ADA Against Feladilimab	Measure Type: Count of Participants Unit of measure: participants [Not specified]	
Week 1	Number Analyzed	69 participants
		1 1.45%
Week 4	Number Analyzed	59 participants
		8 13.56%
Week 7	Number Analyzed	50 participants

		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
		4 8%
Week 10	Number Analyzed	45 participants
		2 4.44%
Week 13	Number Analyzed	36 participants
		2 5.56%
Week 16	Number Analyzed	32 participants
		1 3.12%
Week 19	Number Analyzed	23 participants
		2 8.7%
Week 22	Number Analyzed	19 participants
		0 0%
Week 25	Number Analyzed	17 participants
		0 0%
Week 37	Number Analyzed	11 participants
		0 0%
Week 49	Number Analyzed	3 participants
		0 0%

		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Week 61	Number Analyzed	4 participants
		0 0%
Week 73	Number Analyzed	1 participants
		0 0%

Reported Adverse Events

Time Frame	All cause mortality, non-SAEs and SAEs were collected up to 2 years.
Adverse Event Reporting Description	Safety population included all randomized participants who received at least one dose of SoC or experimental regimen based on actual treatment received.

Reporting Groups

	Description
Docetaxel 75 mg/m^2	Participants with NSLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).
Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Participants with NSLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.

All-Cause Mortality

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total All-Cause Mortality	25/34 (73.53%)		62/70 (88.57%)	

Serious Adverse Events

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	16/34 (47.06%)		34/70 (48.57%)	
Blood and lymphatic system disorders				
Anaemia [A] †	1/34 (2.94%)	1	2/70 (2.86%)	2
Febrile neutropenia [A] †	3/34 (8.82%)	3	4/70 (5.71%)	4
Leukopenia [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Neutropenia [A] †	0/34 (0%)	0	2/70 (2.86%)	2
Pancytopenia [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Cardiac disorders				
Acute coronary syndrome [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Cardiac arrest [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Cardiac failure [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Cardiopulmonary failure [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Right ventricular failure [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Gastrointestinal disorders				
Diarrhoea [A] †	0/34 (0%)	0	2/70 (2.86%)	2
Gastric ulcer perforation [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Pancreatitis acute [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Stomatitis [A] †	0/34 (0%)	0	2/70 (2.86%)	2
General disorders				
Asthenia [A] †	0/34 (0%)	0	2/70 (2.86%)	2
Chest pain [A] †	0/34 (0%)	0	1/70 (1.43%)	3
Fatigue [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Oedema peripheral [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Pain [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Performance status decreased [A] †	0/34 (0%)	0	1/70 (1.43%)	2
Sudden death [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Infections and infestations				

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Bronchitis [A] †	0/34 (0%)	0	1/70 (1.43%)	1
COVID-19 [A] †	0/34 (0%)	0	2/70 (2.86%)	2
Diarrhoea infectious [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Lung abscess [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Pneumocystis jirovecii pneumonia [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Pneumonia [A] †	6/34 (17.65%)	7	7/70 (10%)	7
Pneumonia mycoplasmal [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Pyelonephritis [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Upper respiratory tract infection [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Injury, poisoning and procedural complications				
Femur fracture [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Road traffic accident [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Spinal compression fracture [A] †	1/34 (2.94%)	1	1/70 (1.43%)	1
Investigations				
Troponin increased [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Musculoskeletal and connective tissue disorders				
Back pain [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Bone pain [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Nervous system disorders				
Cerebrovascular accident [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Seizure [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Renal and urinary disorders				
Acute kidney injury [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Renal failure [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Reproductive system and breast disorders				
Pelvic pain [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Respiratory, thoracic and mediastinal disorders				

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Acute respiratory distress Syndrome [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Acute respiratory failure [A] †	1/34 (2.94%)	1	0/70 (0%)	0
Chronic obstructive pulmonary disease [A] †	1/34 (2.94%)	1	1/70 (1.43%)	1
Dyspnoea [A] †	0/34 (0%)	0	1/70 (1.43%)	1
Haemoptysis [A] †	0/34 (0%)	0	2/70 (2.86%)	2
Pneumonitis [A] †	1/34 (2.94%)	1	2/70 (2.86%)	2
Pulmonary embolism [A] †	0/34 (0%)	0	3/70 (4.29%)	3
Respiratory failure [A] †	0/34 (0%)	0	1/70 (1.43%)	1

†Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (25.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	31/34 (91.18%)		66/70 (94.29%)	
Blood and lymphatic system disorders				
Anaemia [A] †	7/34 (20.59%)	9	24/70 (34.29%)	31
Neutropenia [A] †	1/34 (2.94%)	1	12/70 (17.14%)	16
Eye disorders				
Lacrimation increased [A] †	2/34 (5.88%)	2	4/70 (5.71%)	4
Gastrointestinal disorders				
Abdominal pain upper [A] †	2/34 (5.88%)	2	4/70 (5.71%)	4
Constipation [A] †	2/34 (5.88%)	2	13/70 (18.57%)	16
Diarrhoea [A] †	8/34 (23.53%)	12	16/70 (22.86%)	20
Nausea [A] †	6/34 (17.65%)	9	26/70 (37.14%)	45
Stomatitis [A] †	3/34 (8.82%)	3	5/70 (7.14%)	7
Vomiting [A] †	3/34 (8.82%)	3	5/70 (7.14%)	6

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
General disorders				
Asthenia [A] †	10/34 (29.41%)	11	22/70 (31.43%)	27
Chest pain [A] †	2/34 (5.88%)	2	7/70 (10%)	7
Fatigue [A] †	5/34 (14.71%)	5	17/70 (24.29%)	22
Mucosal inflammation [A] †	3/34 (8.82%)	5	4/70 (5.71%)	5
Oedema peripheral [A] †	1/34 (2.94%)	1	5/70 (7.14%)	5
Pain [A] †	1/34 (2.94%)	2	4/70 (5.71%)	4
Pyrexia [A] †	6/34 (17.65%)	8	12/70 (17.14%)	14
Infections and infestations				
Oral candidiasis [A] †	3/34 (8.82%)	3	2/70 (2.86%)	2
Respiratory tract infection [A] †	1/34 (2.94%)	1	5/70 (7.14%)	5
Urinary tract infection [A] †	1/34 (2.94%)	1	4/70 (5.71%)	4
Investigations				
Alanine aminotransferase increased [A] †	3/34 (8.82%)	3	3/70 (4.29%)	5
Aspartate aminotransferase increased [A] †	2/34 (5.88%)	2	2/70 (2.86%)	2
Blood alkaline phosphatase increased [A] †	2/34 (5.88%)	2	5/70 (7.14%)	5
Blood creatinine increased [A] †	1/34 (2.94%)	1	5/70 (7.14%)	7
Blood lactate dehydrogenase increased [A] †	1/34 (2.94%)	1	4/70 (5.71%)	5
Neutrophil count decreased [A] †	2/34 (5.88%)	2	5/70 (7.14%)	9
Weight decreased [A] †	3/34 (8.82%)	3	6/70 (8.57%)	6
White blood cell count decreased [A] †	0/34 (0%)	0	4/70 (5.71%)	10
Metabolism and nutrition disorders				
Decreased appetite [A] †	4/34 (11.76%)	4	19/70 (27.14%)	20
Dehydration [A] †	2/34 (5.88%)	2	2/70 (2.86%)	2
Hyperglycaemia [A] †	0/34 (0%)	0	5/70 (7.14%)	5
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	3/34 (8.82%)	5	7/70 (10%)	7

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Back pain [A] †	5/34 (14.71%)	5	2/70 (2.86%)	2
Muscle spasms [A] †	0/34 (0%)	0	4/70 (5.71%)	4
Myalgia [A] †	3/34 (8.82%)	3	10/70 (14.29%)	13
Nervous system disorders				
Dizziness [A] †	2/34 (5.88%)	2	4/70 (5.71%)	4
Headache [A] †	2/34 (5.88%)	2	4/70 (5.71%)	4
Neuropathy peripheral [A] †	3/34 (8.82%)	4	5/70 (7.14%)	5
Paraesthesia [A] †	3/34 (8.82%)	3	9/70 (12.86%)	11
Psychiatric disorders				
Insomnia [A] †	2/34 (5.88%)	2	4/70 (5.71%)	4
Renal and urinary disorders				
Dysuria [A] †	3/34 (8.82%)	3	0/70 (0%)	0
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	4/34 (11.76%)	4	14/70 (20%)	14
Dyspnoea [A] †	4/34 (11.76%)	5	23/70 (32.86%)	25
Dyspnoea exertional [A] †	2/34 (5.88%)	2	2/70 (2.86%)	2
Haemoptysis [A] †	0/34 (0%)	0	4/70 (5.71%)	5
Skin and subcutaneous tissue disorders				
Alopecia [A] †	7/34 (20.59%)	7	20/70 (28.57%)	20
Nail disorder [A] †	2/34 (5.88%)	2	5/70 (7.14%)	5
Pruritus [A] †	0/34 (0%)	0	7/70 (10%)	7
Rash [A] †	3/34 (8.82%)	3	4/70 (5.71%)	4

†Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (25.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single site data not precede the primary publication of the entire clinical trial.

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