Protocol Registration and Results System

Protocol Registration and Results Preview

This is a rough approximation of how the Protocol Registration and Results will appear on the ClinicalTrials.gov public web site.

Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) - Sub-study 1

ClinicalTrials.gov Identifier: NCT05553808

Recruitment Status: Completed
First Posted: *
Last Update Posted: *

* Date not available in PRS

Sponsor:

GlaxoSmithKline

Collaborators:

iTeos Belgium SA

Information provided by (Responsible Party):

GlaxoSmithKline

ID: 205801-001 Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) - Sub-study 1 NCT05553808

Brief Summary:

This study is a sub-study of the master protocol 205801 (NCT03739710). This sub study has assessed the clinical activity of novel regimen (Feladilimab plus Docetaxel) with SOC (Docetaxel) in participants with NSCLC.

Condition or disease	Intervention/treatment	Phase
Neoplasms	Drug: Docetaxel Drug: Feladilimab	Phase 2

Study Design

Study Type:	Interventional
Actual Enrollment:	105 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants
Actual Study Start Date:	January 24, 2019
Actual Primary Completion Date:	September 23, 2021
Actual Study Completion Date:	September 23, 2021

Arms and Interventions

Arm	Intervention/treatment
Active Comparator: Docetaxel	Drug: Docetaxel Docetaxel was administered as IV infusion.
Experimental: Feladilimab plus Docetaxel	Drug: Docetaxel Docetaxel was administered as IV infusion. Drug: Feladilimab Feladilimab was administered as IV infusion.

Outcome Measures

Primary Outcome Measure:

1. Overall Survival [Time Frame: Up to 2 years]

   Overall survival was calculated as time from randomization to death. Confidence Intervals estimated using the Brookmeyer Crowley method.

Secondary Outcome Measures:

1. Kaplan-Meier Estimates of Overall Survival at 12 and 18 Months [Time Frame: Month 12 and 18]

   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 at each time point was calculated. Confidence Intervals estimated using the Brookmeyer Crowley method.

2. Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD) or Not Evaluable [Time Frame: Up to 2 years]

   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.

3. Kaplan-Meier Estimates of Progression-Free Survival (PFS) [Time Frame: Up to 2 years]

   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.

4. Objective Response Rate [Time Frame: Up to 2 years]

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.

5. Kaplan-Meier Estimates of Duration of Response (DOR) in Participants With Objective Response [Time Frame: Up to 2 years]

   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.

6. Disease Control Rate (DCR) [Time Frame: Up to 2 years]

   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.

7. 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 [Time Frame: Up to 2 years]

   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.

8. Kaplan-Meier Estimates of iRECIST Progression-free Survival (iPFS) [Time Frame: Up to 2 years]

   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

9. iRECIST Objective Response Rate (iORR) [Time Frame: Up to 2 years]

   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.

10. Kaplan-Meier Estimates of iRECIST Duration of Response (iDOR) in Participants With Objective Response [Time Frame: Up to 2 years]

    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.

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

    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.

12. Number of Participants With Maximum Grade Increase in Clinical Chemistry Parameters at Worst Case Post-Baseline [Time Frame: Up to 2 years]

    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.

13. Number of Participants With Maximum Grade Increase in Hematology Parameters at Worst Case Post-Baseline [Time Frame: Up to 2 years]

    Blood samples were collected for assessment of the hematology parameters. Laboratory grades were evaluated using the Common Terminology Criteria for

Hematology results by maximum grade increase (Increase to Grade 3 or Increase to Grade 4) are presented.

14. Number of Participants With Maximum Grade Increase in Vital Signs (Systolic Blood Pressure and Diastolic Blood Pressure) Parameters at Worst Case Post-Baseline [Time Frame: Up to 2 years]

    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.

15. Number of Participants With Vital Signs (Temperature) Parameter Results at Worst Case Post-Baseline [Time Frame: Up to 2 years]

    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.

16. Number of Participants With Vital Signs (Pulse Rate) Parameter Results at Worst Case Post-Baseline [Time Frame: Up to 2 years]

    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.

17. Minimum Observed Concentration (CmIn) of Feladilimab [Time Frame: Week 1]

    Blood samples were collected for assessment of the pharmacokinetic parameters.

18. Maximum Observed Concentration (Cmax) of Feladilimab [Time Frame: Week 1, Week 13 and Week 25]

    Blood samples were collected for assessment of the pharmacokinetic parameters.

19. Maximum Observed Concentration (Cmax) of Docetaxel [Time Frame: Week 1, Week 4, Week 7, Week 10, Week 13, Week 16, Week 19 and Week 22]

    Blood samples were collected for assessment of the pharmacokinetic parameters.

20. Number of Participants With Positive Anti-drug Antibodies (ADA) Against Docetaxel [Time Frame: Up to 2 years]

Eligibility Criteria

Ages Eligible for Study:	18 Years and older
Sexes Eligible for Study:	All
Gender Based:	No
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participants capable of giving signed informed consent/assent.
- Male or female, aged 18 years or older at the time consent is obtained. Participants in Korea must be age 19 years or older at the time consent is obtained.
- Participants with histologically or cytologically confirmed diagnosis of NSCLC (squamous or non-squamous) and

  a) Documented disease progression based on radiographic imaging, during or after a maximum of 2 lines of systemic treatment for locally/regionally advanced recurrent, Stage IIIb/Stage IIIc/Stage IV or metastatic disease. Two components of treatment must have been received in the same line or as separate lines of therapy: i) No more than or less than 1 line of platinum-containing chemotherapy regimen, and ii) No more than or less than 1 line of Programmed cell death ligand 1 (PD[L]1) monoclonal antibody (mAb) containing regimen.

  b) Participants with known BRAF molecular alterations must have had disease progression after receiving the locally available SoC treatment for the molecular alteration.

  c) Participants who received prior anti-PD(L)1 therapy must fulfill the following requirements: i) Have achieved a CR, PR or SD and subsequently had disease progression (per RECIST 1.1 criteria) either on or after completing PD(L)1 therapy ii) Have not progressed or recurred within the first 12 weeks of PD(L)1 therapy, either clinically or per RECIST 1.1 criteria
- Measurable disease, presenting with at least 1 measurable lesion per RECIST 1.1.
- Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) score of 0 or 1.
- A tumor tissue sample obtained at any time from the initial diagnosis of NSCLC to time of study entry is mandatory. Although a fresh tumor tissue sample obtained during screening is preferred, archival tumor specimen is acceptable.
- Adequate organ function as defined in the protocol.
- A male participant must agree to use a highly effective contraception during the treatment period and for at least 120 days after the last dose of study treatment and refrain from donating sperm during this period.

i) Not a woman of childbearing potential (WOCBP) or ii) A WOCBP who agrees to follow the contraceptive guidance during the treatment period and for at least 120 days after the last dose of study treatment.

- Life expectancy of at least 12 weeks.

Exclusion Criteria:

- Participants who received prior treatment with the following therapies (calculation is based on date of last therapy to date of first dose of study treatment):

  a. Docetaxel at any time.
  b. Any of the investigational agents being tested in the current study.
  c. Systemic approved or investigational anticancer therapy within 30 days or 5 half-lives of the drug, whichever is shorter. At least 14 days must have elapsed between the last dose of prior anticancer agent and the first dose of study drug is administered.
  d. Prior radiation therapy: permissible if at least one non-irradiated measurable lesion is available for assessment per RECIST version 1.1 or if a solitary measurable lesion was irradiated, objective progression is documented. A wash out of at least 2 weeks before start of study drug for radiation of any intended use is required.
- Received greater than (>)2 prior lines of therapy for NSCLC, including participants with BRAF molecular alternations.
- Invasive malignancy or history of invasive malignancy other than disease under study within the last 2 years, except
  - Any other invasive malignancy for which the participant was definitively treated, has been disease-free for at least 2 years and in the opinion of the principal investigator and GlaxoSmithKline Medical Monitor will not affect the evaluation of the effects of the study treatment on the currently targeted malignancy, may be included in this clinical trial.
  - Curatively treated non-melanoma skin cancer or successfully treated in situ carcinoma.
- Carcinomatous meningitis (regardless of clinical status) and uncontrolled or symptomatic Central nervous system (CNS) metastases.
- Major surgery less than or equal to (<=) 28 days of first dose of study treatment.
- Autoimmune disease (current or history) or syndrome that required systemic treatment within the past 2 years. Replacement therapies which include physiological doses of corticosteroids for treatment of endocrinopathies (for example, adrenal insufficiency) are not considered systemic treatments.
- Receiving systemic steroids (>10 milligrams [mg]) oral prednisone or equivalent) or other immunosuppressive agents within 7 days prior to first dose of study treatment.
- Prior allogeneic/autologous bone marrow or solid organ transplantation.
- Receipt of any live vaccine within 30 days prior to first dose of study treatment.
- Toxicity from previous anticancer treatment that includes:

b. Toxicity related to prior treatment that has not resolved to <= Grade 1 (except alopecia, hearing loss, endocrinopathy managed with replacement therapy, and peripheral neuropathy which must be <= Grade 2).

- History (current and past) of idiopathic pulmonary fibrosis, pneumonitis (for past-pneumonitis exclusion only if steroids were required for treatment), interstitial lung disease, or organizing pneumonia.
- Recent history (within the past 6 months) of uncontrolled symptomatic ascites, pleural or pericardial effusions.
- Recent history (within the past 6 months) of gastrointestinal obstruction that required surgery, acute diverticulitis, inflammatory bowel disease, or intra-abdominal abscess.
- History or evidence of cardiac abnormalities within the 6 months prior to enrollment which include

  a. Serious, uncontrolled cardiac arrhythmia or clinically significant electrocardiogram abnormalities including second degree (Type II) or third degree atrioventricular block.
  b. Cardiomyopathy, myocardial infarction, acute coronary syndromes (including unstable angina pectoris), coronary angioplasty, stenting or bypass grafting.
  c. Symptomatic pericarditis.
- Current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypo-albuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis.
- Active infection requiring systemic therapy <=7 days prior to first dose of study treatment.
- Participants with known human immunodeficiency virus infection.
- Participants with history of severe hypersensitivity to mAb or hypersensitivity to any of the study treatment(s) or their excipients.
- Participants requiring ongoing therapy with a medication that is a strong inhibitor or inducer of the cytochrome P 3A4 (CYP3A4) enzymes.
- Any serious and/or unstable pre-existing medical (aside from malignancy), psychiatric disorder, or other condition that could interfere with participant's safety, obtaining informed consent, or compliance to the study procedures in the opinion of the investigator.
- Pregnant or lactating female participants.
- Participant who is currently participating in or has participated in a study of an investigational device within 4 weeks prior to the first dose of study treatment.
- Participants with presence of hepatitis B surface antigen (HBsAg) at screening or within 3 months prior to first dose of study intervention.
- Participants with positive hepatitis C antibody test result at screening or within 3 months prior to first dose of study intervention.
- Participants with positive hepatitis C ribonucleic acid (RNA) test result at screening or within 3 months prior to first dose of study treatment.
- Receipt of transfusion of blood products (including platelets or red blood cells) or administration of colony-stimulating factors (including granulocyte colony stimulating factor [G-CSF], granulocyte-macrophage colony-stimulating factor, and recombinant erythropoietin) within 14 days before the first dose of study intervention.

ID: 205801-001 Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) - Sub-study 1 NCT05553808

Locations

United States, Missouri

GSK Investigational Site

Saint Louis, Missouri, United States, 63110-1093

United States, Tennessee

GSK Investigational Site

Nashville, Tennessee, United States, 37203

United States, Texas

GSK Investigational Site

Dallas, Texas, United States, 75230

Canada, Ontario

GSK Investigational Site

Toronto , Ontario , Canada, M5G 2M9

France

GSK Investigational Site

Bordeaux Cedex , France, 33076

GSK Investigational Site

Caen Cedex 9 , France, 14033

GSK Investigational Site

Nantes cedex 1 , France, 44093

GSK Investigational Site

Paris Cedex 05 , France, 75248

GSK Investigational Site

Paris , France, 75018

GSK Investigational Site

Villejuif Cedex , France, 94805

Germany

GSK Investigational Site

Berlin , Germany, 14165

GSK Investigational Site

Gauting , Bayern , Germany

GSK Investigational Site

Immenhausen , Hessen , Germany, 34376

GSK Investigational Site

Leipzig, Sachsen , Germany

GSK Investigational Site

Grosshansdorf , Schleswig-Holstein , Germany, 22927

Italy

GSK Investigational Site

Meldola (FC) , Emilia-Romagna , Italy, 47014

GSK Investigational Site

Ravenna , Emilia-Romagna , Italy, 48121

GSK Investigational Site
Orbassano (TO) , Piemonte , Italy, 10043

Netherlands

GSK Investigational Site
MAASTRICHT , Netherlands, 6229 HX

Poland

GSK Investigational Site
Lodz , Poland, 93-513
GSK Investigational Site
Poznan , Poland, 60-569
GSK Investigational Site
Warszawa , Poland, 02-781

Romania

GSK Investigational Site
Bucharest , Romania, 020142
GSK Investigational Site
Craiova , Romania, 200347
GSK Investigational Site
Floresti , Romania, 407280
GSK Investigational Site
Otopeni , Romania, 075100
GSK Investigational Site
Timisoara , Romania, 300166

Russia

GSK Investigational Site
Chelyabinsk , Russia, 454048
GSK Investigational Site
Saint-Petersburg , Russia, 197183
GSK Investigational Site
Saint-Petersburg , Russia, 194291

South Korea

GSK Investigational Site
Cheongju-si, South Korea, 28644
GSK Investigational Site
Gyeonggi-do, South Korea, 10408
GSK Investigational Site
Seongnam, South Korea, 13620
GSK Investigational Site
Seoul , South Korea, 05505

Spain

GSK Investigational Site
Barcelona , Spain, 08036

GSK Investigational Site
Madrid , Spain, 28033
GSK Investigational Site
Madrid , Spain
GSK Investigational Site
Madrid , Spain, 28027
GSK Investigational Site
Santander , Spain, 39008
GSK Investigational Site
Sevilla , Spain, 41009

Sweden

GSK Investigational Site
Uppsala , Sweden, SE- 75 185

Investigators

Study Director: GSK Clinical Trials GlaxoSmithKline

Study Documents (Full-Text)

Documents provided by GlaxoSmithKline

Study Protocol [PDF] May 23, 2022

Statistical Analysis Plan [PDF] March 8, 2021

More Information

Responsible Party:	GlaxoSmithKline
ClinicalTrials.gov Identifier:	NCT05553808
Other Study ID Numbers:	205801-001 2018-001316-29
Last Verified:	November 2022

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	Yes
Plan Description:	Qualified researchers may request access to anonymized individual patient-level data (IPD) and related study documents of the eligible studies via the Data Sharing Portal. Details on GSK's data sharing criteria can be found at: https://www.gsk.com/en-gb/innovation/trials/data-transparency/

Statistical Analysis Plan (SAP)
Informed Consent Form (ICF)
Clinical Study Report (CSR)

Time Frame:
Anonymized IPD will be made available within 6 months of publication of primary, key secondary and safety results for studies in product with approved indication(s) or terminated asset(s) across all indications.

Access Criteria:
Anonymized IPD is shared with researchers whose proposals are approved by an Independent Review Panel and after a Data Sharing Agreement is in place. Access is provided for an initial period of 12 months but an extension may be granted, when justified, for up to 6 months.

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Study Results

Participant Flow

Recruitment Details	
Pre-assignment Details	

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total (Not public)
Arm/Group Description	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).	Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Period Title: **Overall Study**			
Started	35	70	105

Not Completed	35	70	105
Reason Not Completed			
Death	25	62	87
Site Closed	6	6	12
Lost to Follow-up	1	0	1
Withdrawal by Subject	3	2	5
(Not Public)	Not Completed =35 Total from all reasons =35	Not Completed =70 Total from all reasons =70	

Baseline Characteristics

NOTE : A Study Specific Baseline Measure for an Outcome Measure has not been entered.

Arm/Group Title		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	Total
Arm/Group Description		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).	Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Overall Number of Baseline Participants		35	70	105
Baseline Analysis Population Description [Not specified]				
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	Number Analyzed	35 participants	70 participants	105 participants

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 (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	35 participants		70 participants		105 participants	
	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	

Russia		3	5	8

Outcome Measures

1. Primary Outcome

Title:	Overall Survival
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

Outcome Measure Data

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.

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	35	70
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

Title:	Kaplan-Meier Estimates of Overall Survival at 12 and 18 Months
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 at each time point was calculated. Confidence Intervals estimated using the Brookmeyer Crowley method.
Time Frame:	Month 12 and 18

Outcome Measure Data

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	35	70
Number (95% Confidence Interval) Unit of Measure: Percentage of Participants		
Row Title		
Month 12	44 (27 to 60)	28 (18 to 39)
Month 18	28 (14 to 44)	18 (10 to 28)

3. Secondary Outcome

Title:	Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), Progressive Disease (PD) or Not Evaluable
▼ 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

▼ Outcome Measure Data 

▼ Analysis Population Description
Intent-To-Treat Population.

▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.		Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Overall Number of Participants Analyzed	35		70	
Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
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

Title:	Kaplan-Meier Estimates of Progression-Free Survival (PFS)
▼ 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

▼ Outcome Measure Data 

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2

	Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion once every 3 weeks (Q3W).	feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion once Q3W.
Overall Number of Participants Analyzed	29	62
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

Title:	Objective Response Rate
▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description
Intent-To-Treat Population

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2
▼ Arm/Group Description:	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).	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	35	70
Number (95% Confidence Interval) Unit of Measure: Percentage of Participants	11 (3.2 to 26.7)	19 (10.3 to 29.7)

Title:	Kaplan-Meier Estimates of Duration of Response (DOR) in Participants With Objective Response
▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	4	13
Median (95% Confidence Interval) Unit of Measure: Months	4.8 (2.8 to NA) [1]	4.3 (2.4 to 8.7)

[1] NA Explanation: Upper limit was not calculated due to low number of events

7. Secondary Outcome

Title:	Disease Control Rate (DCR)

	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

▼ Outcome Measure Data

▼ Analysis Population Description
Intent-to-Treat Population.

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	35	70
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

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
▼ 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.
Time Frame:	Up to 2 years

▼ Outcome Measure Data

▼ Analysis Population Description

Arm/Group Title	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.		Participants with NSCLC were administered with Feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Overall Number of Participants Analyzed	35		70	
Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
iCR	0	0%	0	0%
iPR	4	11.43%	13	18.57%
iUPD	11	31.43%	15	21.43%
iCPD	3	8.57%	8	11.43%
iSD	10	28.57%	22	31.43%
Not Evaluable	7	20%	12	17.14%

9. Secondary Outcome

Title:	Kaplan-Meier Estimates of iRECIST Progression-free Survival (iPFS)
▼ 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

▼ Outcome Measure Data ✓

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m2

	Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	29	62
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

Title:	iRECIST Objective Response Rate (iORR)
▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description
Intent-to-Treat population.

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	35	70
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

▼ 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

▼ Outcome Measure Data ✔

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	4	13
Median (95% Confidence Interval) Unit of Measure: Months	4.8 (2.8 to NA) [1]	4.3 (2.4 to 8.7)

[1] NA Explanation: Upper limit was not calculated due to low number of events.

12. Secondary Outcome

Title:	Number of Participants With AEs, Adverse Events of Special Interest (AESI), SAEs and AE/SAEs Leading to Dose Modifications/Delays/Withdrawals

	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

▼ Outcome Measure Data

▼ 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.

Arm/Group Title	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.		Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Overall Number of Participants Analyzed	34		70	
Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
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

▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title		Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:		Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed		34	63
Measure Type: Count of Participants Unit of Measure: participants			
Row Title			
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

Title:	Number of Participants With Maximum Grade Increase in Hematology Parameters at Worst Case Post-Baseline

	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

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.		Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.	
Overall Number of Participants Analyzed	34		64	
Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
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

Title:	Number of Participants With Maximum Grade Increase in Vital Signs (Systolic Blood Pressure and Diastolic Blood Pressure) Parameters at Worst Case Post-Baseline

	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

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.		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.	
Overall Number of Participants Analyzed	34		63	
Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
Diastolic Blood Pressure	12	35.29%	26	41.27%
Systolic Blood Pressure	16	47.06%	28	44.44%

16. Secondary Outcome

Title:	Number of Participants With Vital Signs (Temperature) Parameter Results at Worst Case Post-Baseline
▼ 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

▼ Outcome Measure Data

▼ Analysis Population Description

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

▼ Arm/Group Description:	Participants with NSCLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	34	63
Measure Type: Count of Participants Unit of Measure: participants		
Row Title		
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

Title:	Number of Participants With Vital Signs (Pulse Rate) Parameter Results at Worst Case Post-Baseline
▼ 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

▼ Outcome Measure Data ✔

▼ Analysis Population Description

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

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

Measure Type: Count of Participants Unit of Measure: participants				
Row Title				
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

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

▼ Outcome Measure Data ✔

▼ 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.

Arm/Group Title	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:	Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	67
Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: nanogram per millimeter (ng/mL)	6104.6 (91.3%)

19. Secondary Outcome

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

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Arm/Group Title		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description:		Participants with NSCLC were administered with feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed		67
Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: nanogram per millimeter (ng/mL)		
Row Title		
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

Title:	Maximum Observed Concentration (Cmax) of Docetaxel
▼ 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

▼ Outcome Measure Data ✔

▼ Analysis Population Description

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

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

Geometric Mean (Geometric Coefficient of Variation) Unit of Measure: nanogram per millimeter (ng/mL)			
Row Title			
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%)
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

Title:	Number of Participants With Positive Anti-drug Antibodies (ADA) Against Docetaxel
▼ Description:	[Not specified] NOTE : An Outcome Measure Description has not been entered.
Time Frame:	Up to 2 years

▼ Outcome Measure Data

▼ Analysis Population Description

Data was not collected.

Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2

	Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as intravenous (IV) infusion Q3W.	feladilimab 80 mg IV infusion Q3W in combination with Docetaxel 75 mg/m^2 IV infusion Q3W.
Overall Number of Participants Analyzed	0	0

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

22. Secondary Outcome

Title:	Number of Participants With Positive ADA Against Feladilimab
▼ Description:	[Not specified] NOTE : An Outcome Measure Description has not been entered.
Time Frame:	Week 1, 4, 7, 10, 13, 16, 19, 22, 25, 37, 49, 61 and 73

▼ Outcome Measure Data

▼ Analysis Population Description

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

Arm/Group Title		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
▼ Arm/Group Description:		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.	
Overall Number of Participants Analyzed		69	
Measure Type: Count of Participants Unit of Measure: participants			
Row Title			
Week 1	Number Analyzed	69 participants	
		1	1.45%
Week 4	Number Analyzed	59 participants	
		8	13.56%
Week 7	Number Analyzed	50 participants	
		4	8%
Week 10	Number Analyzed	45 participants	
		2	4.44%

		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%
Week 61	Number Analyzed	4 participants	
		0	0%
Week 73	Number Analyzed	1 participants	
		0	0%

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.	
Source Vocabulary Name for Table Default	MedDRA (25.0)	
Collection Approach for Table Default	Systematic Assessment	
Arm/Group Title	Docetaxel 75 mg/m^2	Feladilimab 80 mg Plus Docetaxel 75 mg/m^2
▼ Arm/Group Description	Participants with NSLC were administered with Docetaxel 75 milligram per meter square (mg/m^2) monotherapy as	Participants with NSLC were administered with feladilimab 80 mg IV infusion once Q3W in combination with Docetaxel

All-Cause Mortality

	Docetaxel 75 mg/m^2		Feladilimab 80 mg Plus Docetaxel 75 mg/m^2	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	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
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

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				
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

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

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	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
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	2/34 (5.88%)	2	2/70 (2.86%)	2

phosphatase increased †A				
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
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

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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