ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: 205801-002 Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) - Sub-study 2 NCT06790303

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 2

ClinicalTrials.gov Identifier:
NCT06790303

Recruitment Status: Terminated (Due to low enrolment of participants)
First Posted: *
Last Update Posted: *

* Date not available in PRS

Sponsor:

GlaxoSmithKline

Information provided by (Responsible Party):

GlaxoSmithKline

Study Description

Brief Summary:

This study is a sub-study of the master protocol 205801 (NCT03739710). This sub study will assess the clinical activity of novel regimen (Feladilimab plus Ipilimumab) in participants with NSCLC.

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

Study Design

Study Type:	Interventional
Actual Enrollment:	8 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label) Click here to enter text.
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:	March 4, 2021
Actual Primary Completion Date:	September 23, 2021
Actual Study Completion Date:	September 23, 2021

Arms and Interventions

Arm	Intervention/treatment
Experimental: Feladilimab plus Ipilimumab	Drug: Feladilimab Feladilimab will be administered. Drug: Ipilimumab Ipilimumab will be administered

Outcome Measures

Primary Outcome Measure:

1. Part 1: Number of Participants With Any Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: Up to 29 weeks]

   An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. SAE is defined as any untoward medical occurrence that, at any dose resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability/incapacity, or is a congenital anomaly/birth defect, other situations which involved medical or scientific judgment or is associated with liver injury and impaired liver function. SAEs are subset of AEs. AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA dictionary).

2. Part 1: Number of Participants With Dose Limiting Toxicities (DLTs) [Time Frame: Up to 21 days]

   Criteria for dose-limiting toxicity (DLT) included hematologic indicators such as febrile neutropenia as defined by CTCAE v5; Grade 4 neutropenia of >7 days in duration; Grade 4 anemia and Grade 3-4 thrombocytopenia with bleeding. Non-hematologic criteria, comprising Grade 4 toxicity; Grade 3 pneumonitis of any duration; Grade 3 toxicity that does not resolve to ≤Grade 1 or baseline within 3 days despite optimal supportive care; any Grade 2 ocular toxicity requiring systemic steroids, or any ≥ Grade 3 ocular toxicity Any other toxicity considered to be dose-limiting that occurs beyond four weeks was considered as DLT. Any other event which in the judgment of the investigator and GSK Medical Monitor is considered to be a DLT.

3. Part 1: Number of Participants With Worst-case Change Post-baseline in Hematology Parameters [Time Frame: Baseline (Day 1) and up to 29 weeks]

   Blood samples were collected for evaluation of hematology parameters. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by CTCAE v5.0. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

4. Part 1: Number of Participants With Worst-case Change Post-baseline in Clinical Chemistry Parameters [Time Frame: Baseline (Day 1) and up to 29 weeks]

   Blood samples were collected for evaluation of clinical chemistry parameters. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

5. Part 1: Number of Participants With Worst Case Change Post-baseline in Urinalysis Parameters [Time Frame: Baseline (Day 1) and up to 29 weeks]

   Urine samples were collected for evaluation of urinalysis parameters using dipstick method. The dipstick test gave results in a semi-quantitative manner. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by CTCAE v5.0. The number of participants with 'Any increase', or 'no changes/decreased' values have been presented.

6. Part 1: Change From Baseline in Potential of Hydrogen (pH) of Urine [Time Frame: Baseline (Day 1), week 4, week 7, week 10, week 13 and week 29 (Treatment Discontinuation)]

   Urine samples were collected from participants to assess urine pH levels. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acid pH (5.0 - 6.0). Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Changes from baseline in urine pH were reported.

7. Part 1: Change From Baseline in Specific Gravity of Urine [Time Frame: Baseline (Day 1), week 4, week 7, week 10, week 13 and week 29 (Treatment Discontinuation)]

   Urine samples were collected from participants to analyze urine specific gravity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.

Changes from baseline in specific gravity of urine were reported.

8. Part 1: Number of Participants With AE Leading to Dose Modifications [Time Frame: Up to 29 weeks]

   An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. The number of participants who experienced AE leading to dose modifications were evaluated.

9. Part 2: Overall Survival [Time Frame: Up to 29 weeks]

   OS is defined as the time from randomization until death due to any cause.

Secondary Outcome Measures:

1. Part 1: Overall Response Rate (ORR) [Time Frame: Up to 29 weeks]

   ORR was defined as the percentage of participants who had a confirmed complete response (CR) or confirmed partial response (PR) as their best overall response (BOR) recorded from the date of randomization until disease progression or initiation of new anti-cancer therapy, whichever is earlier based on blinded independent central review (BICR) evaluation criteria in solid tumors (RECIST) version 1.1 (v1.1). CR was defined as disappearance of all target lesions. Any pathological lymph nodes must be <10 millimeter in the short axis. PR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters (e.g., percent change from baseline).

2. Part 1: Disease Control Rate (DCR) [Time Frame: Up to 29 weeks]

   DCR was defined as the percentage of participants with a confirmed CR + PR at any time, plus stable disease (SD) >=12 weeks. PR was defined as at least 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. CR was defined as the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 mm. Stable Disease (SD) was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease.

3. Part 1: Maximum Concentration (Cmax) and Minimum Concentration (Cmin) [Time Frame: Up to 29 weeks]

   Blood samples were collected for PK analysis.

4. Part 2: Milestone Survival Rate at 12 and 18 Months [Time Frame: At 12 and 18 months]

   Milestone survival rate is the proportion of participants who are alive at a specific, predefined point in time after a certain event or diagnosis post treatment.

5. Part 2: Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), and Progressive Disease (PD) Based on RECIST 1.1 [Time Frame: Up to 29 weeks]

   Complete Response [CR], Partial Response [PR], stable disease [SD], and progressive disease (PD) as assessed by the investigator per IMWG. CR defined as the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 mm; PR was defined as at least 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters; Stable Disease (SD) was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease. PD was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as a reference, the smallest sum of diameters recorded since the treatment started.

6. Part 2: Number of Participants With iRECIST Complete Response (iCR), iRECIST Partial Response (iPR), iRECIST Stable Disease (iSD), iRECIST Confirmed Progressive Disease (iCPD), and iRECIST Unconfirmed Progressive Disease (iUPD) [Time Frame: Up to 29 weeks]

   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 to be 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.

7. Part 2: Number of Participants With PFS, ORR, DOR, and DCR [Time Frame: Up to 29 weeks]

   PFS defined as time from the date of randomization to the date of disease progression or death, whichever will occurs earlier, per RECIST criteria. ORR defined as the percentage of participants with a confirmed CR or PR at any time per RECIST criteria. DOR defined as the time from first documented evidence of CR or PR until disease progression or death, per RECIST criteria. DCR was defined as the percentage of participants with a confirmed CR + PR at any time, plus stable disease (SD) >=12 weeks.

8. Part 2: Number of Participants With iPFS, iORR, and iDOR [Time Frame: Up to 29 weeks]

   iPFS defined as time from the date of randomization to the date of disease progression or death, whichever will occurs earlier, per iRECIST criteria. iORR defined as the percentage of participants with a confirmed iCR or iPR at any time per iRECIST criteria. iDOR defined as the time from first documented evidence of CR or PR until disease progression or death, per iRECIST criteria.

9. Part 2: Number of Participants With AEs and SAEs [Time Frame: Up to 29 weeks]

   An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function. AEs and SAEs were planned to be coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system.

10. Part 2: Number of Participants With AESI [Time Frame: Up to 29 weeks]

    Number of participants with AESI were planned to be evaluated.

11. Part 2: Number of Participants With AEs and SAEs Leading to Dose Modification [Time Frame: Up to 29 weeks]

    An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function. AEs and SAEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system. Number of participants with AEs and SAEs leading to dose modification (delays/withdrawal) were planned to be evaluated.

12. Part 2: Number of Participants With Clinically Significant Changes in Hematology Lab Parameters [Time Frame: Up to 29 weeks]

    Blood samples were to be collected for the analysis of hematology parameters. The laboratory parameters were to be graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5. Grade 1 (G1): mild; Grade 2 (G2): moderate; Grade 3 (G3): severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade were to be defined relative to the Baseline grade.

13. Part 2: Number of Participants With Clinically Significant Changes in Clinical Chemistry Lab Parameters [Time Frame: Up to 29 weeks]

    Blood samples were to be collected for the analysis of chemistry parameters. The laboratory parameters were to be graded according to CTCAE version 5. G1: mild; G2: moderate; G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade were to be defined relative to the Baseline grade.

14. Part 2: Number of Participants With Clinically Significant Changes in Vital Signs [Time Frame: Up to 29 weeks]

    Vital signs were planned to be measured after 5 minutes of rest and taken in the same position throughout the study.

15. Part 2: Maximum Concentration (Cmax) and Minimum Concentration (Cmin) [Time Frame: Up to 29 weeks]

    Blood samples were planned to be collected for PK analysis.

16. Part 2: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Feladilimab [Time Frame: Up to 29 weeks]

    Serum samples were to be collected for the analysis of the presence of ADAs using validated immunoassays.

17. Part 2: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Iplimumab [Time Frame: Up to 29 weeks]

    Serum samples were to be collected for the analysis of the presence of ADAs using validated immunoassays.

Eligibility Criteria

Ages Eligible for Study: 18 Years and older
Sexes Eligible for Study: All
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
- 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 V-Raf Murine Sarcoma Viral Oncogene Homolog B (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.

- A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least 1 of the following conditions apply:

  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):

    1. Docetaxel at any time.
    2. Any of the investigational agents being tested in the current study.
    3. 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.
    4. 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:
    1. Greater than or equal to (>=) Grade 3 toxicity considered related to prior immunotherapy and that led to treatment discontinuation.
    2. 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
    1. Serious, uncontrolled cardiac arrhythmia or clinically significant electrocardiogram abnormalities including second degree (Type II) or third degree atrioventricular block.
    2. Cardiomyopathy, myocardial infarction, acute coronary syndromes (including unstable angina pectoris), coronary angioplasty, stenting or bypass grafting.
    3. 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.

Contacts and Locations

Locations

United States, Tennessee

GSK Investigational Site

Nashville, Tennessee, United States, 37203

Canada, ON

GSK Investigational Site

Brampton, ON, Canada, L6R3J7

France

GSK Investigational Site

Bordeaux, France, 33076

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:	NCT06790303
Other Study ID Numbers:	205801-002 2018-001316-29
Last Verified:	April 2025

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Yes

Plan Description:

Study Sponsor will assess requests from qualified researchers for anonymized individual patient-level data and related study documents. Data sharing is subject to certain criteria, conditions, and exceptions. For further information, refer to https://www.gsk-studyregister.com/About_GSK_Patient_Level_Data_Sharing_Final_13July2023.pdf

More information provided by GlaxoSmithKline

Supporting Materials: Study Protocol
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 asset(s) with development terminated 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	This is a sub-study of the master study NCT03739710. This sub study was terminated due to low enrolment of participants. The study was planned to include two phases - Part 1 and Part 2. No participants from this sub study were enrolled in part 2 as study was early terminated.
Pre-assignment Details	

Arm/Group Title	Feladilimab + Ipilimumab	Total (Not public)
Arm/Group Description	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Period Title: **Overall Study**		
Started	8	8
Completed	0	0
Not Completed	8	8
Reason Not Completed		
Study Terminated by sponsor	4	4
Death	4	4
(Not Public)	Not Completed =8 Total from all reasons =8	

Baseline Characteristics

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

Arm/Group Title		Feladilimab + Ipilimumab
▼ Arm/Group Description		Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Baseline Participants		8
▼ Baseline Analysis Population Description [Not specified]		
Age, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	8 participants
18 to 84 years		8
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants	Number Analyzed	8 participants
	Female	3 37.5%
	Male	5 62.5%
Race/Ethnicity, Customized [1] Measure Type: Number Unit of measure: Participants	Number Analyzed	8 participants
All other races		8
		[1] Measure Description: Race categories (White and Asian where 0<n<11) are combined into 'All other races' category to maintain participant confidentiality and privacy.

Outcome Measures

1. Primary Outcome

Title:	Part 1: Number of Participants With Any Adverse Events (AEs) and Serious Adverse Events (SAEs)
▼ Description:	An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. SAE is defined as any untoward medical occurrence that, at any dose resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent disability/incapacity, or is a congenital anomaly/birth defect, other situations which involved medical or scientific judgment or is associated with liver injury and impaired liver function. SAEs are subset of AEs. AEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA dictionary).

Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Safety Population included all participants who received at least one dose of treatment.

Arm/Group Title	Feladilimab + Ipilimumab	
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed	8	
Measure Type: Count of Participants Unit of Measure: Participants		
Row Title		
Any AE	8	100%
Any SAE	3	37.5%

2. Primary Outcome

Title:	Part 1: Number of Participants With Dose Limiting Toxicities (DLTs)
▼ Description:	Criteria for dose-limiting toxicity (DLT) included hematologic indicators such as febrile neutropenia as defined by CTCAE v5; Grade 4 neutropenia of >7 days in duration; Grade 4 anemia and Grade 3-4 thrombocytopenia with bleeding. Non-hematologic criteria, comprising Grade 4 toxicity; Grade 3 pneumonitis of any duration; Grade 3 toxicity that does not resolve to ≤Grade 1 or baseline within 3 days despite optimal supportive care; any Grade 2 ocular toxicity requiring systemic steroids, or any ≥ Grade 3 ocular toxicity Any other toxicity considered to be dose-limiting that occurs beyond four weeks was considered as DLT. Any other event which in the judgment of the investigator and GSK Medical Monitor is considered to be a DLT.
Time Frame:	Up to 21 days

▼ Outcome Measure Data ✔

▼ Analysis Population Description
Safety Population

Arm/Group Title	Feladilimab + Ipilimumab	
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed	8	
Measure Type: Count of Participants Unit of Measure: Participants	2	25%

3. Primary Outcome

Title:	Part 1: Number of Participants With Worst-case Change Post-baseline in Hematology Parameters
▼ Description:	Blood samples were collected for evaluation of hematology parameters. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by CTCAE v5.0. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.
Time Frame:	Baseline (Day 1) and up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
Safety Population

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion

	(started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed	8	
Measure Type: Count of Participants Unit of Measure: Participants		
Row Title		
Basophils, Decrease to Low	0	0%
Basophils, Change to Normal or No Change	8	100%
Basophils, Increase to High	0	0%
Eosinophils, Decrease to Low	0	0%
Eosinophils, Change to Normal or No Change	7	87.5%
Eosinophils, Increase to High	1	12.5%
Erythrocytes, Decrease to Low	2	25%
Erythrocytes, Change to Normal or No Change	6	75%
Erythrocytes, Increase to High	0	0%
Hemoglobin, Decrease to Low	0	0%
Hemoglobin, Change to Normal or No Change	8	100%
Hemoglobin, Increase to High	0	0%
Ery. Mean Corpuscular HGB Concentration (EMCHC), Decrease to Low	1	12.5%
EMCHC, Change to Normal or No Change	7	87.5%
EMCHC, Increase to High	0	0%
Ery. Mean Corpuscular Hemoglobin (EMCH), Decrease to Low	0	0%
EMCH, Change to Normal or No Change	7	87.5%
EMCH, Increase to High	1	12.5%
Ery. Mean Corpuscular Volume (EMCV), Decrease to Low	0	0%
EMCV, Change to Normal or No Change	7	87.5%
EMCV, Increase to High	1	12.5%
Hematocrit, Decrease to Low	0	0%
Hematocrit, Change to Normal or No Change	8	100%

Hematocrit, Increase to High	0	0%
Leukocytes, Decrease to Low	0	0%
Leukocytes, Change to Normal or No Change	7	87.5%
Leukocytes, Increase to High	1	12.5%
Lymphocytes, Decrease to Low	0	0%
Lymphocytes, Change to Normal or No Change	8	100%
Lymphocytes, Increase to High	0	0%
Monocytes, Decrease to Low	0	0%
Monocytes, Change to Normal or No Change	7	87.5%
Monocytes, Increase to High	1	12.5%
Neutrophils, Decrease to Low	0	0%
Neutrophils, Change to Normal or No Change	6	75%
Neutrophils, Increase to High	2	25%
Platelets, Decrease to Low	1	12.5%
Platelets, Change to Normal or No Change	6	75%
Platelets, Increase to High	1	12.5%

4. Primary Outcome

Title:	Part 1: Number of Participants With Worst-case Change Post-baseline in Clinical Chemistry Parameters
▼ Description:	Blood samples were collected for evaluation of clinical chemistry parameters. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. The number of participants with decreases to low from baseline, changes to normal or no changes from baseline, and increases to high values have been presented. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date.
Time Frame:	Baseline (Day 1) and up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description

Safety Population. Only those participants with data available in specified categories have been analyzed.

Arm/Group Title	Feladilimab + Ipilimumab

▼ Arm/Group Description:		Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed		8	
Measure Type: Count of Participants Unit of Measure: Participants			
Row Title			
Alanine aminotransferase (ALT), Decrease to Low	Number Analyzed	8 participants	
		0	0%
ALT, Change to Normal or No Change	Number Analyzed	8 participants	
		6	75%
ALT, Increase to High	Number Analyzed	8 participants	
		2	25%
Albumin, Decrease to Low	Number Analyzed	8 participants	
		2	25%
Albumin, Change to Normal or No Change	Number Analyzed	8 participants	
		6	75%
Albumin, Increase to High	Number Analyzed	8 participants	
		0	0%
Alkaline Phosphatase (AP), Decrease to Low	Number Analyzed	8 participants	
		0	0%
AP, Change to Normal or No Change	Number Analyzed	8 participants	
		8	100%
AP, Increase to High	Number Analyzed	8 participants	
		0	0%
Aspartate Aminotransferase (AST), Decrease to Low	Number Analyzed	8 participants	
		0	0%
AST, Change to Normal or No Change	Number Analyzed	8 participants	
		8	100%
AST, Increase to High	Number Analyzed	8 participants	
		0	0%
Bilirubin, Decrease to Low	Number Analyzed	8 participants	
		0	0%
Bilirubin, Change to Normal or No Change	Number Analyzed	8 participants	
		8	100%
Bilirubin, Increase to High	Number Analyzed	8 participants	
		0	0%

C Reactive Protein (mg/L), Decrease to Low	Number Analyzed	3 participants	
		0	0%
C Reactive Protein, Change to Normal or No Change	Number Analyzed	3 participants	
		3	100%
C Reactive Protein, Increase to High	Number Analyzed	3 participants	
		0	0%
Calcium, Decrease to Low	Number Analyzed	8 participants	
		0	0%
Calcium, Change to Normal or No Change	Number Analyzed	8 participants	
		7	87.5%
Calcium, Increase to High	Number Analyzed	8 participants	
		1	12.5%
Creatinine, Decrease to Low	Number Analyzed	8 participants	
		1	12.5%
Creatinine, Change to Normal or No Change	Number Analyzed	8 participants	
		6	75%
Creatinine, Increase to High	Number Analyzed	8 participants	
		1	12.5%
Glucose, Decrease to Low	Number Analyzed	8 participants	
		0	0%
Glucose, Change to Normal or No Change	Number Analyzed	8 participants	
		7	87.5%
Glucose, Increase to High	Number Analyzed	8 participants	
		1	12.5%
Lactate Dehydrogenase (LDH), Decrease to Low	Number Analyzed	8 participants	
		0	0%
LDH, Change to Normal or No Change	Number Analyzed	8 participants	
		8	100%
LDH, Increase to High	Number Analyzed	8 participants	
		0	0%
Potassium, Decrease to Low	Number Analyzed	8 participants	
		1	12.5%
Potassium, Change to Normal or No Change	Number Analyzed	8 participants	
		7	87.5%
Potassium, Increase to High	Number Analyzed	8 participants	
		0	0%
Protein, Decrease to Low	Number Analyzed	8 participants	

		1	12.5%
Protein, Change to Normal or No Change	Number Analyzed	8 participants	
		7	87.5%
Protein, Increase to High	Number Analyzed	8 participants	
		0	0%
Sodium, Decrease to Low	Number Analyzed	8 participants	
		1	12.5%
Sodium, Change to Normal or No Change	Number Analyzed	8 participants	
		7	87.5%
Sodium, Increase to High	Number Analyzed	8 participants	
		0	0%
Thyrotropin, Decrease to Low	Number Analyzed	7 participants	
		0	0%
Thyrotropin, Change to Normal or No Change	Number Analyzed	7 participants	
		5	71.43%
Thyrotropin, Increase to High	Number Analyzed	7 participants	
		2	28.57%
Triiodothyronine, Free, Decrease to Low	Number Analyzed	4 participants	
		1	25%
Triiodothyronine, Free, Change to Normal or No Change	Number Analyzed	4 participants	
		3	75%
Triiodothyronine, Free, Increase to High	Number Analyzed	4 participants	
		0	0%
Troponin T, Decrease to Low	Number Analyzed	3 participants	
		0	0%
Troponin T, Change to Normal or No Change	Number Analyzed	3 participants	
		2	66.67%
Troponin T, Increase to High	Number Analyzed	3 participants	
		1	33.33%
Urea, Decrease to Low	Number Analyzed	8 participants	
		0	0%
Urea, Change to Normal or No Change	Number Analyzed	8 participants	
		3	37.5%
Urea, Increase to High	Number Analyzed	8 participants	
		5	62.5%

5. Primary Outcome

Title:	Part 1: Number of Participants With Worst Case Change Post-baseline in Urinalysis Parameters
▼ Description:	Urine samples were collected for evaluation of urinalysis parameters using dipstick method. The dipstick test gave results in a semi-quantitative manner. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. The summaries of worst-case change from Baseline with respect to normal range have been presented for only those laboratory tests that are gradable by CTCAE v5.0. The number of participants with 'Any increase', or 'no changes/decreased' values have been presented.
Time Frame:	Baseline (Day 1) and up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description

Safety Population. Only those participants with data available in specified categories have been analyzed.

Arm/Group Title	Feladilimab + Ipilimumab	
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed	6	
Measure Type: Count of Participants Unit of Measure: Participants		
Row Title		
Occult Blood, No Change/Decreased	6	100%
Protein, Any Increase	3	50%
Protein, No Change/Decreased	3	50%

6. Primary Outcome

Title:	Part 1: Change From Baseline in Potential of Hydrogen (pH) of Urine
▼ Description:	Urine samples were collected from participants to assess urine pH levels. pH is measured on a numeric scale ranging from 0 to 14; values on the scale refer to the degree of alkalinity or acidity. A pH of 7 is neutral. A pH less than 7 is acidic, and a pH greater than 7 is basic. Normal urine has a slightly acid pH (5.0 - 6.0). Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Changes from baseline in urine pH were reported. If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline (Day 1), week 4, week 7, week 10, week 13 and week 29 (Treatment Discontinuation)

▼ 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 + Ipilimumab
▼ Arm/Group Description:		Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed		6
Mean (Standard Deviation) Unit of Measure: Potential of Hydrogen (pH)		
Row Title		
Baseline (Day 1)	Number Analyzed	6 participants
		6.33 (0.816)
WEEK 4	Number Analyzed	5 participants
		-0.80 (0.975)
WEEK 7	Number Analyzed	2 participants
		-0.50 (0.707)
WEEK 10	Number Analyzed	1 participants
		0.00 (0.00)
WEEK 13	Number Analyzed	1 participants
		0.50 (NA) [1]
WEEK 29 (Treatment Discontinuation)	Number Analyzed	3 participants
		-0.50 (0.866)

[1] NA Explanation: Standard deviation was not estimable for single participant.

7. Primary Outcome

Title:	Part 1: Change From Baseline in Specific Gravity of Urine
▼ Description:	Urine samples were collected from participants to analyze urine specific gravity. Baseline was defined as the most recent, non-missing value prior to or on the first study treatment dose date. Changes from baseline in specific gravity of urine were reported.
Time Frame:	Baseline (Day 1), week 4, week 7, week 10, week 13 and week 29 (Treatment Discontinuation)

▼ 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 + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).

Overall Number of Participants Analyzed		6
Mean (Standard Deviation) Unit of Measure: Kilogram per cubic meter		
Row Title		
Baseline (Day 1)	Number Analyzed	6 participants
		1.0175 (0.00418)
WEEK 4	Number Analyzed	5 participants
		0.0050 (0.01173)
WEEK 7	Number Analyzed	2 participants
		0.0150 (0.01414)
WEEK 10	Number Analyzed	1 participants
		0.0000 (0.0000)
WEEK 13	Number Analyzed	1 participants
		0.0250 (NA) [1]
WEEK 29 (Treatment Discontinuation)	Number Analyzed	3 participants
		0.0017 (0.00764)

[1] NA Explanation: Standard deviation was not estimable for single participant.

8. Primary Outcome

Title:	Part 1: Number of Participants With AE Leading to Dose Modifications
▼ Description:	An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. The number of participants who experienced AE leading to dose modifications were evaluated.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
Safety Population

Arm/Group Title	Feladilimab + Ipilimumab	
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).	
Overall Number of Participants Analyzed	8	
Measure Type: Count of Participants Unit of Measure: Participants	1	12.5%

9. Primary Outcome

Title:	Part 2: Overall Survival

▼ Description:	OS is defined as the time from randomization until death due to any cause.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

10. Secondary Outcome

Title:	Part 1: Overall Response Rate (ORR)
▼ Description:	ORR was defined as the percentage of participants who had a confirmed complete response (CR) or confirmed partial response (PR) as their best overall response (BOR) recorded from the date of randomization until disease progression or initiation of new anti-cancer therapy, whichever is earlier based on blinded independent central review (BICR) evaluation criteria in solid tumors (RECIST) version 1.1 (v1.1). CR was defined as disappearance of all target lesions. Any pathological lymph nodes must be <10 millimeter in the short axis. PR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters (e.g., percent change from baseline).
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
Safety Population

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	8
Number (95% Confidence Interval) Unit of Measure: Percentage of participants	
Row Title	
Complete response	0 (0 to 0)
Partial response	0 (0 to 0)

11. Secondary Outcome

Title:	Part 1: Disease Control Rate (DCR)
▼ Description:	DCR was defined as the percentage of participants with a confirmed CR + PR at any time, plus stable disease (SD) >=12 weeks. PR was defined as at least 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. CR was defined as the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 mm. 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 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
Safety population. No participants had CR, PR, and SD.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

12. Secondary Outcome

Title:	Part 1: Maximum Concentration (Cmax) and Minimum Concentration (Cmin)
▼ Description:	Blood samples were collected for PK analysis. NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
PK Population included all participants from the ITT Population from whom a blood sample is obtained and analyzed for PK concentration. Data was not collected and analyzed.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

13. Secondary Outcome

Title:	Part 2: Milestone Survival Rate at 12 and 18 Months
▼ Description:	Milestone survival rate is the proportion of participants who are alive at a specific, predefined point in time after a certain event or diagnosis post treatment.
Time Frame:	At 12 and 18 months

▼ Outcome Measure Data ✔

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

14. Secondary Outcome

Title:	Part 2: Number of Participants With Complete Response (CR), Partial Response (PR), Stable Disease (SD), and Progressive Disease (PD) Based on RECIST 1.1
▼ Description:	Complete Response [CR], Partial Response [PR], stable disease [SD], and progressive disease (PD) as assessed by the investigator per IMWG. CR defined as the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to less than (<)10 mm; PR was defined as at least 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters; Stable Disease (SD) was defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease. PD was defined as at least a 20% increase in the sum of the diameters of target lesions, taking as a reference, the smallest sum of diameters recorded since the treatment started.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

15. Secondary Outcome

Title:	Part 2: Number of Participants With iRECIST Complete Response (iCR), iRECIST Partial Response (iPR), iRECIST Stable Disease (iSD), iRECIST Confirmed Progressive Disease (iCPD), and iRECIST Unconfirmed Progressive Disease (iUPD)
▼ 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 to be 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.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

16. Secondary Outcome

Title:	Part 2: Number of Participants With PFS, ORR, DOR, and DCR
▼ Description:	PFS defined as time from the date of randomization to the date of disease progression or death, whichever will occurs earlier, per RECIST criteria. ORR defined as the percentage of participants with a confirmed CR or PR at any time per RECIST criteria. DOR defined as the time from first documented evidence of CR or PR until disease progression or death, per RECIST criteria. DCR was defined as the percentage of participants with a confirmed CR + PR at any time, plus stable disease (SD) >=12 weeks.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion

	(started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

17. Secondary Outcome

Title:	Part 2: Number of Participants With iPFS, iORR, and iDOR
▼ Description:	iPFS defined as time from the date of randomization to the date of disease progression or death, whichever will occurs earlier, per iRECIST criteria. iORR defined as the percentage of participants with a confirmed iCR or iPR at any time per iRECIST criteria. iDOR defined as the time from first documented evidence of CR or PR until disease progression or death, per iRECIST criteria.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description

No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

18. Secondary Outcome

Title:	Part 2: Number of Participants With AEs and SAEs
▼ Description:	An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function. AEs and SAEs were planned to be coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description

No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab

▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

19. Secondary Outcome

Title:	Part 2: Number of Participants With AESI
▼ Description:	Number of participants with AESI were planned to be evaluated.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

20. Secondary Outcome

Title:	Part 2: Number of Participants With AEs and SAEs Leading to Dose Modification
▼ Description:	An adverse event (AE) is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. SAE is defined as any untoward medical occurrence that; results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect, other situations judged by physician, is associated with liver injury and impaired liver function. AEs and SAEs were coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system. Number of participants with AEs and SAEs leading to dose modification (delays/withdrawal) were planned to be evaluated.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab

▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

21. Secondary Outcome

Title:	Part 2: Number of Participants With Clinically Significant Changes in Hematology Lab Parameters
▼ Description:	Blood samples were to be collected for the analysis of hematology parameters. The laboratory parameters were to be graded according to Common Terminology Criteria for Adverse Events (CTCAE) version 5. Grade 1 (G1): mild; Grade 2 (G2): moderate; Grade 3 (G3): severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade were to be defined relative to the Baseline grade.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description

No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

22. Secondary Outcome

Title:	Part 2: Number of Participants With Clinically Significant Changes in Clinical Chemistry Lab Parameters
▼ Description:	Blood samples were to be collected for the analysis of chemistry parameters. The laboratory parameters were to be graded according to CTCAE version 5. G1: mild; G2: moderate; G3: severe or medically significant. Higher grade indicates greater severity and an increase in CTCAE grade were to be defined relative to the Baseline grade.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description

No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

23. Secondary Outcome

Title:	Part 2: Number of Participants With Clinically Significant Changes in Vital Signs
▼ Description:	Vital signs were planned to be measured after 5 minutes of rest and taken in the same position throughout the study.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

24. Secondary Outcome

Title:	Part 2: Maximum Concentration (Cmax) and Minimum Concentration (Cmin)
▼ Description:	Blood samples were planned to be collected for PK analysis. NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✔

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).

Overall Number of Participants Analyzed	0

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

25. Secondary Outcome

Title:	Part 2: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Feladilimab
▼ Description:	Serum samples were to be collected for the analysis of the presence of ADAs using validated immunoassays. NOTE : Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description

No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

26. Secondary Outcome

Title:	Part 2: Number of Participants With Post-baseline Positive Anti-drug Antibodies (ADAs) Against Iplimumab
▼ Description:	Serum samples were to be collected for the analysis of the presence of ADAs using validated immunoassays.
Time Frame:	Up to 29 weeks

▼ Outcome Measure Data ✓

▼ Analysis Population Description
No participants were enrolled in Part 2 as study was terminated.

Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description:	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).
Overall Number of Participants Analyzed	0

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

Adverse Events

Time Frame	All cause mortality, non-serious adverse events (Non-SAEs) and serious adverse events (SAEs) were collected up to 29 weeks.
Adverse Event Reporting Description	Safety Population included all participants who received at least one dose of treatment.
Source Vocabulary Name for Table Default	MedDRA v24.1
Collection Approach for Table Default	Systematic Assessment
Arm/Group Title	Feladilimab + Ipilimumab
▼ Arm/Group Description	Participants with Non-Small Cell Lung Cancer (NSCLC) received 24 milligram (mg) Feladilimab first as a 30-minute intravenous (IV) infusion followed by 1 mg/ kilogram (kg) Ipilimumab as IV infusion (started at least 30 minutes following the end of the feladilimab) once every 3 weeks (Q3W).

All-Cause Mortality

	Feladilimab + Ipilimumab
	Affected / at Risk (%)
Total	4/8 (50%)

▼ **Serious Adverse Events**

	Feladilimab + Ipilimumab

	Affected / at Risk (%)	# Events
Total	3/8 (37.5%)	
General disorders		
Pyrexia † A	1/8 (12.5%)	1
Infections and infestations		
Pneumonia staphylococcal † A	1/8 (12.5%)	1
Injury, poisoning and procedural complications		
Overdose † A	1/8 (12.5%)	1
Metabolism and nutrition disorders		
Hypercalcaemia † A	1/8 (12.5%)	1
Nervous system disorders		
Spinal cord compression † A	1/8 (12.5%)	1
Subacute inflammatory demyelinating polyneuropathy † A	1/8 (12.5%)	1
Psychiatric disorders		
Confusional state † A	1/8 (12.5%)	1
Respiratory, thoracic and mediastinal disorders		
Pneumonia aspiration † A	1/8 (12.5%)	1

† Indicates events were collected by systematic assessment.
A Term from vocabulary, v24.1

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
	Feladilimab + Ipilimumab	
	Affected / at Risk (%)	# Events
Total	8/8 (100%)	
Blood and lymphatic system disorders		
Anaemia † A	2/8 (25%)	2
Lymphopenia † A	1/8 (12.5%)	2
Gastrointestinal disorders		
Abdominal distension † A	1/8 (12.5%)	1
Abdominal pain † A	2/8 (25%)	2
Constipation † A	2/8 (25%)	2
General disorders		
General physical health deterioration † A	1/8 (12.5%)	1
Infections and infestations		
Bronchitis † A	1/8 (12.5%)	1
Oral fungal infection † A	1/8 (12.5%)	1
Pneumonia klebsiella † A	1/8 (12.5%)	1
Metabolism and nutrition disorders		
Hypercalcaemia † A	1/8 (12.5%)	1
Hypoalbuminaemia † A	1/8 (12.5%)	1
Hyponatraemia † A	1/8 (12.5%)	1
Musculoskeletal and connective tissue disorders		
Arthralgia † A	2/8 (25%)	2
Back pain † A	1/8 (12.5%)	1
Nervous system disorders		

Cerebellar ataxia † A	1/8 (12.5%)	1
Memory impairment † A	1/8 (12.5%)	1
Nervous system disorder † A	1/8 (12.5%)	1
Psychiatric disorders		
Confusional state † A	1/8 (12.5%)	1
Psychomotor retardation † A	1/8 (12.5%)	1
Respiratory, thoracic and mediastinal disorders		
Pleuritic pain † A	1/8 (12.5%)	1
Pneumonitis † A	1/8 (12.5%)	1
Skin and subcutaneous tissue disorders		
Dry skin † A	1/8 (12.5%)	1
Rash † A	1/8 (12.5%)	1
Urticaria † A	1/8 (12.5%)	1

† Indicates events were collected by systematic assessment.
A Term from vocabulary, v24.1

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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