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ClinicalTrials.gov ID: NCT05553808

Study Identification

Unique Protocol ID:	205801-001
Brief Title:	Platform Trial of Novel Regimens Versus Standard of Care (SoC) in Participants With Non-small Cell Lung Cancer (NSCLC) - Sub-study 1
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
Secondary IDs:	2018-001316-29 [EudraCT Number]

Study Status

Record Verification:	December 2022
Overall Status:	Completed
Study Start:	January 24, 2019 [Actual]
Primary Completion:	September 23, 2021 [Actual]
Study Completion:	September 23, 2021 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	Sponsor
Collaborators:	iTeos Belgium SA

Oversight

U.S. FDA-regulated Drug:	Yes
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CBER IND/IDE Number: 138944 Serial Number: Has Expanded Access: No
Human Subjects Review:	Board Status: Approved Approval Number: 11/8/2018 Board Name: MARY CROWLEY MEDICAL RESEARCH CENTER INSTITUTIONAL REVIEW BOARD Board Affiliation: Mary Crowley Medical Research Center Phone: 2146581962 Email: Address: Building C, 7777 Forest Ln #707, Dallas, TX 75230
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

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.
Detailed Description:	

Conditions

Conditions:	Neoplasms
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	None (Open Label)
Allocation:	Randomized
Enrollment:	105 [Actual]

Arms and Interventions

Arms	Assigned Interventions
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

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	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.
- 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):

  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.
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Toxicity from previous anticancer treatment that includes:

a. Greater than or equal to (>=) Grade 3 toxicity considered related to prior immunotherapy and that led to treatment discontinuation.
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.
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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.

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IPDSharing

Plan to Share IPD: Yes

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/

Supporting Information:

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 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.

URL: https://www.gsk.com/en-gb/innovation/trials/data-transparency/

References

Citations:

Links:

Available IPD/Information: