GSK 205801 - (dernière mise à jour : 06/08/2019)

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Informations générales

Titre de l'étude : Etude de phase II, en plateforme, randomisée, en ouvert, utilisant un « Master protocol » pour évaluer de nouveaux schémas thérapeutiques versus le traitement standard chez des patients atteints d'un cancer du poumon non à petites cellules (CPNPC)

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : II **Stade** : Localement avancé à Métastatique **Ligne(s)** : 2, 3

Schéma : This study will compare the clinical activity of novel immune-oncology agents (in combination or as single agents) to standard of care in participants with relapsed/refractory advanced NSCLC. The study will initially evaluate two treatment regimens/arms. Additional regimens/arms may be added via future protocol amendment(s). Participants will be stratified by histology (squamous vs. non-squamous) and line of anti-programmed cell death ligand 1 (PD[L]1) therapy (first vs. second line). Initially, the study will evaluate the GSK3359609 inducible T-cell co-stimulator (ICOS) agonist in combination with SoC docetaxel compared to docetaxel alone (sub-study 1). SoC arm will be the common comparison arm across all sub-studies. At study start, subjects will be randomized to the study at a ratio of 1:2 to Arm 1 (docetaxel) and Arm 2 (ICOS agonist + docetaxel). The study will consist of three periods: Screening, Treatment, and Follow-Up. There will be approximately 105 participants enrolled in the study initially. Treatment will continue for approximately 2 years and participants will be followed for survival during the follow-up period.

2 treatment arms:
- Experimental: Subjects receiving GSK3359609 (ICOS Agonist) + Docetaxel
Subjects will receive the combination once every 3 weeks as an IV infusion. Subjects receiving docetaxel will be premedicated according to approved product label or standard practice.
- Active Comparator: Subjects receiving Docetaxel
Subjects will receive docetaxel once in every 3 weeks as an intravenous infusion.

Spécialités / Localisations

Spécialité n°1 : Organes respiratoires et intrathoraciques

CIM10 - Localisation n°1 : **C34** - Tumeur maligne des bronches et du poumon

Critères

Critères d'inclusion : - Subjects capable of giving signed informed consent/assent.
- Male or female, aged 18 years or older at the time consent is obtained.
- Subjects with histologically or cytologically confirmed diagnosis of NSCLC (squamous or non-squamous) and: a. Documented disease progression (for example, based on radiographic imaging) during or after a maximum of 2 lines of systemic treatment for locally/regionally advanced recurrent, Stage IIIb/Stage IV or metastatic disease: i. A maximum of 1 line of platinum-containing chemotherapy regimen in the metastatic setting, and ii. A maximum of 1 line of 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. Participants with this alteration could have received up to 3 lines of systemic anticancer therapy.

- Measurable disease, presenting with at least 1 measurable lesion per RECIST 1.1.
- ECOG 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.
- A male subject 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 subject is eligible to participate if she is not pregnant, not breastfeeding, and at least 1 of the following conditions apply: a) Not a woman of childbearing potential (WOCBP) or 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.

Critères de non-inclusion : - Subjects 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, including experimental ICOS agonist. 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 >=3 prior lines of therapy for NSCLC, including subjects with BRAF molecular alternations.
- Invasive malignancy or history of invasive malignancy other than disease under study within the last 2 years.
- Central nervous system (CNS) metastases, with the following exception: Subjects with asymptomatic CNS metastases who are clinically stable and have no requirement for steroids for at least 14 days prior to first dose of study treatment.
- Major surgery <= 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 milligram [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: a. >= 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.
- History or evidence of cardiac abnormalities within the 6 months prior to enrollment.
- 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.
- Subjects with known human immunodeficiency virus infection, or positive test for hepatitis B active infection (presence of hepatitis B surface antigen), or hepatitis C active infection.
- Subjects with history of severe hypersensitivity to monoclonal antibodies or hypersensitivity to ingredients used in the formulation of docetaxel.
- Subjects requiring ongoing therapy with a medication that is a strong inhibitor or inducer of the cytochrome 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 subjects.
- Subject is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment.

Informations promoteur

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03739710?intr=GSK3359609&rank=3