KEYNOTE-598 - MK-3475-598 (dernière mise à jour : 19/09/2019)

http://archimaid.fr/index.php?action=show&id=254

Informations générales

Titre de l'étude : A Phase 3, Randomized, Double-Blind Study of Pembrolizumab Plus Ipilimumab vs Pembrolizumab Plus Placebo in Previously Untreated, Stage IV, Metastatic Non-small Cell Lung Cancer Subjects Whose Tumors Are PD-L1 Positive (TPS ? 50%)

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : III **Stade** : Localement avancé à Métastasique **Ligne(s)** : 1

Schéma : Brief Summary
The purpose of this study is to determine the efficacy of pembrolizumab given in combination with either ipilimumab or placebo as first-line treatment in participants with metastatic non-small cell lung cancer (NSCLC). The primary hypothesis of this study is that overall survival (OS) and/or progression-free survival (PFS) is prolonged in participants who receive pembrolizumab and ipilimumab compared to those who receive pembrolizumab and placebo.

Study Arms
•Experimental: pembrolizumab + ipilimumab
Participants receive 200 mg of pembrolizumab by intravenous (IV) infusion on Day 1 of each 3-week cycle for up to 35 cycles of treatment plus 1 mg/kg of ipilimumab by IV infusion on Day 1 of each 6-week cycle for up to 18 cycles of treatment.
Interventions:
?Biological: pembrolizumab
?Biological: ipilimumab

•Active Comparator: pembrolizumab + placebo
Participants receive 200 mg of pembrolizumab by IV infusion on Day 1 of each 3-week cycle for up to 35 cycles of treatment plus placebo by IV infusion on Day 1 of each 6-week cycle for up to 18 cycles of treatment.
Interventions:
?Biological: pembrolizumab
?Other: placebo for ipilimumab

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 : •Has a histologically or cytologically confirmed diagnosis of Stage IV metastatic NSCLC (American Joint Committee on Cancer version 8)
•Has measurable disease per RECIST 1.1 as determined by investigator
•Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
•Has a life expectancy of >3 months
•Has provided archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion not previously

irradiated
•Female participants of childbearing potential must have a negative serum pregnancy test within 72 hours prior to receiving the first dose of study therapy
•Female and male participants of reproductive potential must agree to use contraception starting from the first dose of study medication, throughout the study period, and for up to 120 days after the last dose of study medication
•Male participants must refrain from donating sperm starting from the first dose of study medication, throughout the study period, and for up to 120 days after the last dose of study medication

Critères de non-inclusion : •Has received prior systemic chemotherapy/other targeted or biological antineoplastic therapy treatment for their Stage IV metastatic NSCLC
•Has a tumor that harbors an epidermal growth factor receptor (EGFR)-sensitizing (activating) mutation or an anaplastic lymphoma kinase (ALK) translocation
•Is currently participating in or has participated in a trial of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study therapy
•Has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), Programmed Cell Death Receptor Ligand 1 (anti-PD-L1), or anti- Programmed Cell Death Receptor Ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, CD137)
•Has received prior radiotherapy within 2 weeks of start of study therapy or received lung radiation therapy of >30 Gray (Gy) within 6 months of the first dose of study therapy
•Has recovered from all radiation-related toxicities, does not require corticosteroids, and has not had radiation pneumonitis
•Is receiving systemic steroid therapy <=7 days prior to the first dose of study therapy or receiving any other form of immunosuppressive medication
•Has a known additional malignancy that is progressing or has required active treatment within the past 3 years with the exception of curatively treated basal cell carcinoma of the skin, squamous cell carcinoma of the skin and/or curatively resected in situ cancers
•Has known untreated central nervous system (CNS) metastases and/or carcinomatous meningitis
•Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs)
•Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (i.e., doses exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior the first dose of study therapy
•Has a history of (non-infectious) pneumonitis that required systemic steroids or current pneumonitis/interstitial lung disease
•Has had an allogeneic tissue/solid organ transplant
•Has received a live vaccine within 30 days prior to the first dose of study therapy
•Has an active infection requiring systemic therapy
•Has a known history of human immunodeficiency virus (HIV) infection
•Has a known history of hepatitis B or known active hepatitis C virus infection
•Has a known history of active tuberculosis
•Has known psychiatric or substance abuse disorders that would interfere with cooperating with the requirements of the trial
•Is a regular user of any illicit drugs or had a recent history of substance abuse
•Is pregnant or breast feeding or expecting to conceive or father starting from the first dose of study medication, throughout the study period, and for up to 120 days after the last dose of study medication
•Has severe hypersensitivity to pembrolizumab and/or any of its excipients and/or to ipilimumab and/or any of its excipients
•Has a ROS1 translocation

Informations promoteur

Nom du promoteur : MERCK

Type de promoteur : Industriel

Adresse : - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Hospitalier Universitaire de Lille

Adresse : 2 Avenue Oscar Lambret 59000 LILLE

Investigateur : Professeur Arnaud Scherpereel

TEC / ARC / IDE : Marie Grammont / Eric Wasielewski - *Mail :* eric.wasielewski@chru-lille.fr - *Tél :* 03.20.44.56.12

Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/study/NCT03302234