ILLUMINATE-301 - 2125-MEL-301 (dernière mise à jour : 05/02/2020)

http://archimaid.fr/index.php?action=show&id=368

Informations générales

Titre de l'étude : A Randomized Phase 3 Comparison of IMO-2125 With Ipilimumab Versus Ipilimumab Alone in Subjects With Anti-PD-1 Refractory Melanoma

Traitement : Métastasique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : III **Stade** : Localement avancé à Métastasique **Ligne(s)** : 2, 3, 4, X

Schéma : A Phase 3 global, multi-center, open-label comparison of ipilimumab with and without intratumoral IMO-2125 in subjects with advanced melanoma who had confirmed disease progression while on nivolumab or pembrolizumab

Spécialités / Localisations

Spécialité n°1 : Peau

CIM10 - Localisation n°1 : **C43** - Mélanome malin de la peau

Critères

Critères d'inclusion : 1. Subjects must be willing and able to sign the informed consent and comply with the study protocol.
2. Subjects must be >=18 years of age.
3. Subjects must have histologically confirmed metastatic melanoma with measurable (by RECIST v1.1), stage III (lymph node or in transit lesions) or stage IVA, IVB, or IVC disease that is accessible for injection.
4. Patients must have confirmed progression during or after treatment with either nivolumab or pembrolizumab. Confirmed progression is defined as:
? Radiological progression (confirmed at least 4 weeks after
the initial scan showing PD); or
? (For progression based solely on worsening of non-target or new, non-measurable disease) confirmation by an additional scan at least 4 weeks after the initial scan unless it is accompanied by correlative symptoms.
In addition, all the following must hold:
. No intervening anti-cancer therapy between the last course of nivolumab or pembrolizumab and the first dose of study treatment is allowed except for local measures (e.g., surgical excision or biopsy, focal radiation therapy).
. The interval between last nivolumab or pembrolizumab and start of study treatment should be at least 21 days with no residual anti-PD-1-related immune toxicities in excess of Grade 1 severity.
. If BRAF mutation status is unknown, before randomization the subject must have BRAF testing performed using an approved assay method.
. Patients with BRAF-positive tumor(s) are eligible for the study if they received prior treatment with a BRAF inhibitor (alone of in combination with a MEK inhibitor) or declined targeted therapy.
5. Patients must have Eastern Cooperative Oncology Group (ECOG) Performance Status <= 1.
6. Patients must meet the following laboratory criteria:
. Absolute neutrophil count (ANC) >= 1.5 x 10^9/L
(1500/mm3)
. Platelet count >= 75 x 10^9/L (75,000/mm3)
. Hemoglobin >= 8.0 g/dL (4.96 mmol/L)

. Serum creatinine <= 1.5 x upper limit of normal (ULN) or calculated creatinine clearance >= 60 mL/minute
. Aspartate aminotransferase (AST) <= 2.5 x ULN; alanine aminotransferase (ALT) <= 2.5 x ULN; AST/ALT < 5 x ULN if liver involvement
. Serum bilirubin <= 1.5 x ULN, except in subjects with Gilbert's Syndrome who must have a total bilirubin < 3 mg/dL
7. Women of childbearing potential (WOCBP) and men must agree to use effective contraceptive methods from Screening throughout the study treatment period and until at least 90 days after the last dose of either ipilimumab or IMO-2125, whichever is later.
8. WOCBP must have a negative pregnancy test (serum or urine).

Critères de non-inclusion : 1. Ocular melanoma.
2. Prior therapy with a toll-like receptor (TLR) agonist, excluding topical agents.
3. Prior ipilimumab treatment with the exception of adjuvant treatment completed >=6 months prior to enrollment
4. Systemic treatment with interferon (IFN)-? within the previous 6 months.
5. Known hypersensitivity to any oligodeoxynucleotide.
6. Active autoimmune disease requiring disease-modifying therapy at the time of Screening.
7. Subjects requiring systemic steroid therapy should be receiving <= 10 mg/day of prednisone (or equivalent) for the 2 weeks preceding start of study.
8. Subjects with another primary malignancy that has not been in remission for at least 3 years, with the exception of nonmelanoma skin cancer, curatively treated localized prostate cancer with non-detectable prostate-specific antigen, cervical carcinoma in situ on biopsy or a squamous intraepithelial lesion
on Papanicolaou (Pap) smear, and thyroid cancer (except anaplastic).
9. Active systemic infections requiring antibiotics
10. Active hepatitis A, B, or C infection.
11. Known diagnosis of human immunodeficiency virus (HIV) infection.
12. Women who are pregnant or breastfeeding.
13. Prior severe reaction to treatment with a human antibody that cannot be managed with standard supportive measures.
14. Known central nervous system, meningeal, or epidural disease. However, subjects with known brain metastases are allowed if the brain metastases are stable for >=4 weeks before the first dose of study treatment.
15. Impaired cardiac function or clinically significant cardiac disease.

Informations promoteur

Nom du promoteur : Idera Pharmaceuticals, Inc.

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03445533