KEYNOTE-629 - MK-3475-629 (dernière mise à jour : 21/10/2019)

http://archimaid.fr/index.php?action=show&id=377

Informations générales

Titre de l'étude : A Phase 2, Open-Label, Single Arm Study to Evaluate the Safety and Efficacy of Pembrolizumab in Participants With Recurrent or Metastatic Cutaneous Squamous Cell Carcinoma (R/M cSCC)

Traitement : Métastatique ou localement avancé

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

Phase : II **Stade** : Localement avancé à Métastasique **Ligne(s)** : 1, 2, 3, 4, X

Schéma : The purpose of this study is to evaluate the safety and efficacy of pembrolizumab (MK-3475) in adult participants with recurrent or metastatic(R/M) cutaneous Squamous Cell Carcinoma (cSCC) or locally advanced (LA) unresectable cSCC that is not amenable to surgery and/or radiation and/or systemic therapies.

Study Arms :
- Experimental: R/M cSCC cohort
Participants with R/M cSCC receive pembrolizumab 200 mg via intravenous (IV) infusion on Day 1 of each 3-week cycle for up to approximately 2 years.
- Experimental: LA cSCC cohort
Participants with LA cSCC receive pembrolizumab 200 mg via IV infusion on Day 1 of each 3-week cycle for up to approximately 2 years.

Spécialités / Localisations

Spécialité n°1 : Peau

CIM10 - Localisation n°1 : **C44** - Autres tumeurs malignes de la peau

Critères

Critères d'inclusion : R/M cSCC cohort only:
- Has cSCC that is either metastatic defined as disseminated disease, and/or unresectable disease that is not curable by surgery, radiation, or systemic therapy.
- Has histologically-confirmed cSCC as the primary site of malignancy (metastatic skin involvement from another primary cancer or from an unknown primary cancer is not permitted).
LA cSCC cohort only:
- Must be ineligible for surgical resection.
- Participants who received prior radiation therapy (RT) to index site or must be deemed to be not eligible for RT unless the lesion has grown since receiving the RT.
- Participants who received prior systemic therapy for curative intent are eligible regardless of regimen.
R/M cSCC cohort only:
- Has metastatic disease defined as disseminated disease distant to the initial/primary site of diagnosis, and/or must have locally recurrent disease that has been previously treated (with either surgery, radiotherapy, or systemic therapy), and is not amenable to either curative surgery, radiotherapy, or concurrent chemoradiotherapy treatment.
- Has measurable disease based on RECIST 1.1 as assessed by the central imaging vendor.
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 10 days prior to the start of study

treatment.
- Has adequate organ function.
- Has a tissue sample adequate for programmed death-ligand 1 (PD-L1) testing as determined by central laboratory testing prior to study allocation.
- Has a life expectancy >3 months.
- Female participants of childbearing potential must agree to use an adequate method of contraception during the study treatment period and for at least 120 days after the last dose of study treatment.

Critères de non-inclusion : - Has cSCC that is amenable to surgical resection, local control with radiotherapy, or local control with a combination of surgery and radiotherapy, or chemoradiotherapy.
- Has any other histologic type of skin cancer other than invasive squamous cell carcinoma as the primary disease under study, e.g. basal cell carcinoma that has not been definitively treated with surgery or radiation, Bowen's disease, Merkel cell carcinoma (MCC), melanoma.
- Has had any prior allogeneic solid organ or bone marrow transplantation.
- Has received prior therapy with an anti-programmed death protein-1 (anti-PD-1), anti-programmed death-ligand 1 (anti-PD-L1), or anti-PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T cell receptor (e.g. cytotoxic T-lymphocyte associated protein 4 [CTLA-4], Tumor necrosis factor receptor superfamily, member 4 [OX-40], tumor necrosis factor receptor superfamily member 9 [CD137]).
- Has received prior systemic anti-cancer therapy including investigational agents within 4 weeks prior to study allocation. (Notes: Participants must have recovered from all AEs due to previously administered therapies to <= Grade 1 or baseline. If a participant received major surgery, they must have recovered adequately from the toxicity and/or complications from the intervention prior to starting study treatment.)
- Has received prior radiotherapy within 2 weeks of start of study treatment.
- 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.
- Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis.
- Has an active autoimmune disease that has required systemic treatment in the past 2 years (e.g. with use of disease-modifying agents, anticoagulants, corticosteroids or immunosuppressive drugs).
- Has a history of (noninfectious) pneumonitis that required steroids or has current pneumonitis.
- 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.
- Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study treatment.

Informations promoteur

Nom du promoteur : MERCK

Type de promoteur : Industriel

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Coordonnateur : - *Mail :* - *Tél :*

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Investigateur : Professeur Laurent MORTIER

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Statut de l'essai : CLOS

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03284424