MK-3475-630 - KEYNOTE 630 (dernière mise à jour : 06/08/2019)

http://archimaid.fr/index.php?action=show&id=552

Informations générales

Titre de l'étude : Étude de phase III, randomisée, en double aveugle, évaluant le pembrolizumab versus placebo en tant que thérapie adjuvante, après chirurgie et radiothérapie, chez des patients ayant un carcinome épidermoïde cutané, localement avancé, à haut risque

Traitement : Adjuvant

Type d'étude : Ciblage moléculaire / Innovation thérapeutique

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

Schéma : This is a randomized, double-blind, study that compares pembrolizumab with placebo given as adjuvant therapy in participants with high-risk locally advanced cutaneous squamous cell carcinoma (LA cSCC) that have undergone surgery with curative intent in combination with radiotherapy. The primary hypothesis is that pembrolizumab is superior to placebo in increasing recurrence free survival (RFS).

2 treatment arms:
- Experimental: Pembrolizumab
Participants receive 400 mg pembrolizumab by intravenous (IV) infusion administered on Day 1 of each 42-day cycle (Q6W) for up to 9 cycles. Participants that complete 9 cycles of pembrolizumab and experience biopsy-proven-disease recurrence may be eligible to receive up to 18 additional cycles of pembrolizumab in an open-label design.
- Placebo Comparator: Placebo
Participants receive placebo by IV infusion administered on Day 1 of each 42-day cycle (Q6W) for up to 9 cycles. Participants treated with placebo who experience biopsy-proven-disease recurrence may be eligible to receive up to 18 cycles of pembrolizumab in an open-label design.

Spécialités / Localisations

Spécialité n°1 : Peau

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

Critères

Critères d'inclusion : - Has histologically confirmed cutaneous squamous cell carcinoma (cSCC) as the primary site of malignancy (metastatic skin involvement from another primary cancer or from an unknown primary cancer is not permitted)
- Has histologically confirmed LA cSCC with >=1 high-risk feature(s) as the primary site of malignancy
- Has undergone complete macroscopic resection of all known cSCC disease with or without microscopic positive margins
- Has completed adjuvant radiotherapy (RT) for LA cSCC with last dose of RT >=4 weeks and <=16 weeks from randomization
- Has completed at least 50 Gray (Gy) 25 fractions of adjuvant RT for LA cSCC prior to study entry
- Is disease free as assessed by the investigator with complete radiographic staging assessment <=28 days from randomization
- Is not pregnant or breastfeeding
- Is not a woman of childbearing potential (WOCBP)
- Has a negative pregnancy test <=72 hours before the first dose of study intervention
- Has provided an archival or newly-obtained tumor tissue sample adequate for Programmed Cell Death Ligand 1 (PD-L1) testing as determined by central laboratory testing

- Has a life expectancy of >3 months
- Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 <=10 days prior to the first dose of study intervention

Critères de non-inclusion : - Has macroscopic residual cSCC after surgery and/or recurrence with active cSCC disease before randomization
- Has any other histologic type of skin cancer other than invasive cSCC (eg, basal cell carcinoma) that has not been definitively treated with surgery or radiation; Bowen's disease; Merkel cell carcinoma; or melanoma
- Has received prior therapy with an anti-programmed cell death receptor 1(PD-1), anti- PD-L1, or anti-programmed cell death receptor ligand 2 (PD-L2) agent or with an agent directed to another co-stimulatory or co-inhibitory T-cell receptor (eg, cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, CD137)
- Has received prior systemic anticancer therapy including investigational agents for cSCC <=4 weeks prior to randomization
- Has not recovered from all radiation-related toxicities; has not required corticosteroids; and has not had radiation pneumonitis
- Has received a live vaccine <=30 days prior to the first dose of study intervention
- Is currently participating in or has participated in a study of an investigational agent or has used an investigational device <=4 weeks prior to the first dose of study intervention
- Has an active autoimmune disease that has required systemic treatment in past 2 years (ie, with use of disease modifying agents, corticosteroids or immunosuppressive drugs)
- Has a history of (non-infectious) 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 (defined as hepatitis B surface antigen [HBsAg] reactive) or known active hepatitis C virus (HCV; defined as HCV RNA [qualitative] is detected) 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 intervention
- Has had an allogeneic tissue/solid organ transplant

Informations promoteur

Nom du promoteur : MSD (Merck Sharp & Dohme Corp.)

Type de promoteur : Industriel

Adresse : - 00000 HORS FRANCE

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

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Investigateur : Andreea STEFAN

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT03833167?titles=mk-3475-630&cntry=FR&rank=1