



Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants With High-risk Locally Advanced Cutaneous Squamous Cell Carcinoma
Protocole ID	MK-3475-630/KEYNOTE-630
ClinicalTrials.gov ID	NCT03833167
Type(s) de cancer	Peau
Phase	Phase III
Stade	Localement avancé
Type étude	Clinique
Médicament	Pembrolizumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Investigateur principal	Dr Nathaniel Bouganim
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Statut	Actif en recrutement
But étude	This is a randomized, double-blind, study that compares pembrolizumab (MK-3475) 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).
Critères d'éligibilité	<ul style="list-style-type: none">• Has histologically confirmed cutaneous squamous cell carcinoma (cSCC) as the primary site of malignancy (metastatic skin involvement from another type of 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. For those participants with residual microscopic positive margin involvement, confirmation that additional re-excision is not possible must be provided• Has completed adjuvant radiotherapy (RT) for LA cSCC with last dose of RT ≥4 weeks and ≤16 weeks from randomization• Has received an adequate post-op dose of RT (either hypofractionated or conventional)• 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 d'exclusion

- 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 before start of study intervention.
- Has not recovered from all radiation-related toxicities and has not had radiation pneumonitis
- Has received a live vaccine ≤ 30 days prior to the first dose of study intervention
- Has received an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment.
- Has known additional malignancy that is progressing or has required active treatment within the past 2 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin or carcinoma in situ, excluding carcinoma in situ of the bladder, that have undergone potentially curative therapy are not excluded. Other exceptions may be considered with Sponsor consultation. Note: Participants with low risk early-stage prostate cancer defined as below are not excluded: Stage T1c or T2a with a Gleason score ≤ 6 and a prostate-specific antigen (≤ 10 ng/ml) either treated with definitive intent or untreated in active surveillance that has been stable for the past year prior to study allocation. Early stage asymptomatic CLL without prior treatment and without any of the risk features (unmutated IGHV, lymphocytes $>15,000/\mu\text{L}$, palpable lymph nodes) will be eligible for the study
- Has an active autoimmune disease that has required systemic treatment in past 2 years except replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid).
- Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
- 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