Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Traitement adjuvant par le pembrolizumab versus un placebo chez des patients atteints d'un mélanome de stade II à risque élevé ayant été réséqué : Étude de phase 3 à répartition aléatoire et à double insu
Protocole ID	MK-3475-716 (KEYNOTE-716)
ClinicalTrials.gov ID	NCT03553836
Type(s) de cancer	Mélanome
Phase	Phase III
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dr Wilson Miller
Coordonnateur	Amine Saad 514-340-8222 poste 24599
Statut	Fermé
But étude	This 2-part study will evaluate the safety and efficacy of pembrolizumab (MK-3475) compared to placebo in participants with surgically resected high-risk Stage II melanoma. Participants in Part 1 will receive either pembrolizumab or placebo in a double-blind design for up to 17 cycles. Participants who receive placebo or who stop treatment after receiving 17 cycles of pembrolizumab in Part 1, do not experience disease recurrence within 6 months of completing pembrolizumab in Part 1, and do not stop treatment with pembrolizumab for disease recurrence or intolerability, may be eligible to receive up to 35 additional cycles of pembrolizumab in Part 2 in an open-label design. The primary hypothesis of this study is that pembrolizumab increases recurrence-free survival (RFS) compared to placebo.
Critères d'éligibilité	• Has surgically resected and histologically/pathologically confirmed new diagnosis of Stage IIB or IIC cutaneous melanoma per American Joint Committee on Cancer (AJCC) 8th edition guidelines • Has not been previously treated for melanoma beyond complete surgical resection of the current primary melanoma lesion • Has ≤12 weeks between surgical resection and first study treatment • Has no evidence of metastatic disease on imaging as determined by investigator • Has a performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale or Lansky Play-Performance Scale ≥50 for children up to and including 16 years of age at the time of enrollment • Has recovered adequately from toxicity and/or complications from surgery prior to study start • Male participants must agree to use contraception during the treatment period and for at least 120 days after the last dose of study treatment and refrain from donating sperm during this period • Female participants must not be pregnant or breastfeeding, and must agree to use contraception during the treatment period and for at least 120 days after the last dose of study treatment if they are a woman of childbearing potential (WOCBP)

Critères d'exclusion	• Has a known additional malignancy that is progressing or has required active antineoplastic therapy (including hormonal) or surgery treatment within the past 5 years with the exception of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, non-ulcerated primary melanoma <1 mm in depth with no nodal involvement, or carcinoma in situ (e.g., breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy • Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment • Has recovered adequately from major surgery or the toxicity and/or complications from the intervention prior to starting study treatment • WOCBP who has a positive urine pregnancy test within 72 hours prior to randomization or treatment allocation. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required • Has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), anti-Programmed Cell Death Receptor Ligand 1 (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 (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137) • Has received prior systemic anti-cancer therapy for melanoma including investigational agents • Has received a live vaccine within 30 days prior to the first dose 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 severe hypersensitivity (≥Grade 3) to any excipients of pembrolizumab • Has an active autoimmune disease that has required systemic treatment in the past 2 years • 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 reactive) or known active Hepatitis C virus (defined as Hepatitis C virus ribonucleic acid ((RNA)) [qualitative] is detected) infection • Has a history of active tuberculosis (Bacillus tuberculosis) • Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the study, interfere with the participant's participation for the full duration of the study, or is not in the best interest of the participant to participate, in the opinion of the treating investigator • Has a known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study • 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 • Has had an allogeneic tissue/solid organ transplant