Essai Clinique

Généré le 28 avr. 2024 à partir de http://www.geoq.info/fr/pub/essai-clinique-3695-pdf

Titre	Étude de phase II portant sur l'administration du durvalumab et du trémélimumab à des patients qui ont une tumeur rare au stade avancé
Protocole ID	IND.228
ClinicalTrials.gov ID	NCT02879162
Type(s) de cancer	Autre
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	durvalumab et trémélimumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
Investigateur principal	Dr Thierry Alcindor
Coordonnateur	Marie-Claude Joncas 514-934-1934 poste 34906
Statut	Fermé
But étude	The standard or usual treatment for this disease may be chemotherapy or other types of treatment to slow the spread of the disease and relieve some symptoms of this cancer.
Critères d'éligibilité	• Patients must have histologically and/or cytologically confirmed cancer that is advanced / metastatic / recurrent or unresectable and for which no curative therapy exists as follows: • Salivary carcinoma (excluding adenoid cystic carcinoma histology) • Carcinoma of unknown primary with tumour infiltrating lymphocytes (TILs) and/or expressing PD-L1 • Mucosal melanoma • Acral melanoma • Osteosarcoma • Undifferentiated pleomorphic sarcoma • Clear cell carcinoma of the ovary • Squamous cell carcinoma of the anal canal (SCCA) • All patients must have a tumour tissue from their primary or metastatic tumour available • Presence of clinically and/or radiologically documented disease. All radiology studies must be performed within 28 days prior to registration (within 35 days if negative). • All patients must have at least one measurable lesion as defined by RECIST 1.1 that has not been the site of the protocol mandated biopsy. The criteria for defining measurable disease are as follows: • CT scan (with slice thickness of 5 mm) ≥ 10 mm --> longest diameter Lymph nodes by CT scan ≥ 15 mm --> measured in short axis • Patients must be ≥ 16 years of age. • Patients must have an ECOG performance status of 0 or 1. • Previous Therapy • Cytotoxic Chemotherapy: • Patients may have received prior chemotherapy - no limit on number of prior regimens. • Other Systemic Therapy: • Patients may have received other prior therapies including, angiogenesis inhibitors, PARP

	inhibitors or signal transduction inhibitors (tyrosine kinase inhibitors). Prior therapy with PD-1/PD-L1 or CTLA-4 inhibitors is not allowed. • Patients must have recovered from all reversible toxicity related to prior chemotherapy or systemic therapy (unless grade 1, irreversible, or considered by investigator as not clinically significant) and have adequate washout as follows: • Longest of one of the following: • Two weeks • 5 half-lives for investigational agents • Standard cycle length of standard therapies • Radiation: • Prior external beam radiation is permitted provided a minimum of 28 days (4 weeks) have elapsed between the last dose of radiation and date of registration. Exceptions may be made for low-dose, non-myelosuppressive radiotherapy after consultation with CCTG senior investigator. Concurrent radiotherapy is not permitted. Patients planned for concurrent chemotherapy-radiation are not eligible. • Surgery: • Previous surgery is permitted provided that a minimum of 28 days (4 weeks) have elapsed between any major surgery and date of registration, and that wound healing has occurred. • Lab Requirements: • Absolute neutrophils ≥ 1.5 x 10^9/L Platelets ≥ 100 x 10^9/L Hemoglobin ≥ 90 g/L Bilirubin ≤ 1.5 x ULN (upper limit of normal)* AST and ALT ≤ 2.5 x ULN (if liver metastases are present, ≤ 5 x ULN) Serum creatinine < 1.25 x ULN or: Creatinine clearance ≥ 40 mLs/min • Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements • Women/men of childbearing potential must have agreed to use a highly effective contraceptive method. • Patients must be accessible for treatment and follow up. Patients registered on this trial must be treated and followed at the participating centre. • Subjects should not donate blood while participating in this study, or for at least 90 days following the last infusion of durvalumab or tremelimumab. • In accordance with CCTG policy, protocol treatment is to begin within 2 working days of patient registration
Critères d'exclusion	• Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other cancers curatively treated with no evidence of disease for ≥ 5 years. • Active or prior documented autoimmune or inflammatory disorders including inflammatory bowel disease (e.g. colitis or Crohn's disease), diverticulitis with the exception of diverticulosis, celiac disease or other serious gastrointestinal chronic conditions associated with diarrhea), systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome (granulomatosis with polyangiitis), rheumatoid arthritis, hypophysitis, uveitis, etc., within the past 3 years prior to the start of treatment. The following are exceptions to this criterion: • Patients with alopecia. • Patients with Grave's disease, vitiligo or psoriasis not requiring systemic treatment (within the last 2 years). • Patients with hypothyroidism (e.g. following Hashimoto syndrome) stable on hormone replacement. • History of primary immunodeficiency, history of allogenic organ transplant that requires therapeutic immunosuppression and the use of immunosuppressive agents within 28 days of registration. • Live attenuated vaccination administered within 30 days prior to registration. • History of hypersensitivity to durvalumab or tremelimumab or any excipient. Any previous treatment with a PD1 or PD-L1 inhibitor, including durvalumab or an anti-CTLA4, including tremelimumab. • Patients who have experienced untreated and/or uncontrolled cardiovascular conditions and/or have symptomatic cardiac dysfunction (unstable angina, congestive heart failure, myocardial infarction within the previous year or cardiac ventricular arrhythmias requiring medication, history of 2nd or 3rd degree atrioventricular conduction defects). Patients with a significant cardiac history, even if controlled, should have a LVEF ≥ 50%. • Untreated symptomatic brain metastases or brain metastases in whom radiation or surgery is indicated. • Concurrent treatment with other investigational drugs or anti-cancer therapy. • Patients with serious illnesses or medical conditions which would not permit the patient to be managed according to the protocol (incl corticosteroid administration), or would put the patient at risk. This includes but is not limited to: • History of significant neurologic or psychiatric disorder which would impair the ability to obtain consent or limit compliance with study requirements. • Active infection requiring systemic therapy; (including any patient known to have active hepatitis B, hepatitis C or human immunodeficiency virus (HIV) or tuberculosis or any infection requiring systemic therapy). • Active peptic ulcer disease or gastritis. • Known pneumonitis or pulmonary fibrosis with clinically significant impairment of pulmonary function. • Pregnant or lactating women.