Essai Clinique

Généré le 17 mai 2025 à partir de

Titre	Étude d'augmentation de la dose et d'expansion de la cohorte de phase 1 sur le TSR-042, un anticorps monoclonal anti-PD-1, chez des patients présentant des tumeurs solides avancées
Protocole ID	GARNET
ClinicalTrials.gov ID	NCT02715284
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	TSR-042
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
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Statut	Actif en recrutement
Date d'activation	25-07-2017
But étude	This is a multicenter, open-label, first-in-human Phase 1 study evaluating the anti-programmed death receptor 1 (anti-PD-1) antibody TSR-042 in patients with advanced solid tumors who have limited available treatment options. The study will be conducted in 2 parts: dose escalation and cohort expansion. The cohort expansion may include up to 5 tumor types, including endometrial and Non-Small Cell Lung cancer.
Critères d'éligibilité	• Patient is at least 18 years of age • Patient with advanced or metastatic solid tumor and has disease progression after treatment with available therapies that are known to confer clinical benefit or who are intolerant to treatment that meets the following requirements for the part of the study they will participate in: 1. Part 1: Patient with any advanced or metastatic solid tumor 2. Part 2A: Patient with any advanced or metastatic solid tumor 3. Part 2B: Patient with Non-Small Cell Lung Cancer (NSCLC) and Endometrial cancers • Female patients, if of childbearing potential, must have a negative serum pregnancy test within 72 hours prior to the date of the first dose of study medication. • Female patients of childbearing potential must agree to use 2 adequate methods of contraception with their partner starting with the screening visit through 150 days after the last dose of study therapy. • Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2 for Part 1 and ≤ 1 for Part 2. Adequate organ function.

Critères d'exclusion	• Patient has received prior therapy with an anti- programmed death receptor 1 (anti-PD-1), anti-PD-1- ligand-1 (anti-PD-L1), or anti-PD-1 ligand-2 (anti-PD- L2) agent. • Known uncontrolled central nervous system (CNS) metastases and/or carcinomatous meningitis. Note: Patients with previously treated brain metastases may participate provided they are stable (without evidence of progression by imaging for at least 4 weeks prior to the first dose of study treatment and any neurologic symptoms have returned to baseline), have no evidence of new or enlarging brain metastases, and are clinically stable off steroids for at least 7 days prior to study treatment. Carcinomatous meningitis precludes a patient from study participation regardless of clinical stability. • Known additional malignancy that progressed or required active treatment within the last 2 years. Exceptions include basal cell carcinoma of the skin, squamous cell cancer (SqCC) of the skin that has undergone potentially curative therapy, or in situ cervical cancer. • Known history of human immunodeficiency virus (HIV) (HIV 1/2 antibodies). • Known active hepatitis B (eg, hepatitis B surface antigen [HBsAg] reactive) or hepatitis C (eg, hepatitis C virus ribonucleic acid (HCV RNA) (qualitative) is detected). • Active autoimmune disease that has required systemic treatment in the past 2 years (ie, with use of disease- modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. • History of interstitial lung disease.