Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Phase 1/2 Open-label, First-in-human, Dose Escalation and Expansion Study for the Evaluation of Safety, Pharmacokinetics, Pharmacodynamics, and Anti-tumor Activity of SAR444200-based Regimen in Participants With Advanced Solid Tumors.
Protocole ID	TCD17240
ClinicalTrials.gov ID	NCT05450562
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	SAR444200 en monothérapie ou avec cémiplimab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
Investigateur principal	Dr Maxime Chénard-Poirier
Coordonnateur	Marie-Pierre Brochu 418-525-4444 poste 15768
Statut	Actif en recrutement
Date d'activation	06-07-2022
But étude	This is a single group, treatment, Phase 1/Phase 2, open label, multiple cohort, first-in-human study to evaluate safety and efficacy of SAR444200 as a monotherapy or in combination with other anti-cancer agents for participants aged at least 18 years with previously treated metastatic malignancies.
Critères d'éligibilité	• Cancer diagnosis for participants for Part 1A and Part 1B: 1. Metastatic and/or unresectable HCC diagnosed by histology and/or cytology, or diagnosed clinically by the American Association for the Study of Liver Diseases (AASLD) criteria for participants with liver cirrhosis (participants without liver cirrhosis must be diagnosed histologically) OR Other histology/cytology proven advanced and/or metastatic non-HCC solid tumors 2. Not amenable to available standard of care: participants must have experienced disease progression on/after standard of care, or no acceptable standard curative or palliative treatments exist (or are no longer effective), according to Investigator judgement, or the patient declines standard of care therapy. • Cancer diagnosis for participants for Part 2A: Metastatic NSCLC diagnosed by histology and/or cytology not amenable to available standard of care • Additional for Part 2A: At least 1 measurable lesion per RECIST 1.1 criteria • For all participants: 1. Positive GPC3 expression on tumor tissue as determined locally or centrally 2. Capable of giving signed informed consent

Critères d'exclusion	• Eastern Cooperative Oncology Group (ECOG) performance status of ≥2. • Predicted life expectancy ≤3 months. • For participants with HCC: Child Pugh Class B or C liver score within 14 days of initiation of IMP. Participants with Child Pugh Class B-7 score are allowed for Part 1A. • Known active brain metastases or leptomeningeal metastases. • History of allogenic or solid organ transplant • Treatment-related immune-mediated (or immune-related) AEs from immune-modulatory agents (including but not limited to anti-PD1/PD-L1 agents and anti-cytotoxic T lymphocyte associated protein 4 monoclonal antibodies) that caused permanent discontinuation of the agent, or that were Grade 4 in severity • Significant cardiovascular disease within 3 months prior to initiation of IMP, uncontrolled arrhythmia requiring medication, or unstable angina. • Ongoing AEs caused by any prior anti-cancer therapy >Grade 2 • Known uncontrolled human immunodeficiency virus (HIV), hepatitis B infection, or known untreated current hepatitis C infection • Known second malignancy either progressing or requiring active treatment within the last year. • For combination therapy: Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments, which may suggest risk for immune-related adverse events • Receipt of a live-virus vaccination within 28 days of planned treatment start. • For Part 2A, has received prior GPC3 targeted anticancer treatment. • Current pneumonitis or interstitial lung disease, or history of interstitial lung disease or pneumonitis that required oral or IV glucocorticoids to assist with management. NOTE: Other Inclusion/Exclusion criteria may apply. The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.