Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Multicenter, Open-label, Phase 2, Basket Study to Evaluate the Efficacy and Safety of SKB264 in Combination With Pembrolizumab in Subjects With Selected Solid Tumors
Protocole ID	SKB264-II-06
ClinicalTrials.gov ID	NCT05642780
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Type étude	Clinique
Médicament	SKB264 en association avec le pembrolizumab
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Diane Provencher
Coordonnateur	Adeline Hamon 514-890-8000 poste 30737
Statut	Actif en recrutement
Date d'activation	17-10-2023
But étude	The purpose of this study is to evaluate the efficacy and safety of combination of SKB264 and Pembrolizumab in patients with selected solid tumors including cervical cancer, urothelial cancer, ovarian cancer, prostate cancer.
Critères d'éligibilité	• Subjects with Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 . • Subjects with expected survival ≥ 3 months. • Cohort A: Subjects with recurrent or metastatic cervical cancer • Cohort B: Subjects with locally advanced or metastatic urothelial carcinoma • Cohort C: Subjects with recurrent ovarian cancer • Cohort D: Subjects with metastatic prostate cancer • Subjects have at least one measurable lesion per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria. • Subjects able to provide tumor blocks or slides for biomarker test. • Subjects have relatively good organ function and bone marrow function. • Subjects must have recovered from all toxicities from previous therapy with the exception of toxicities not considered a safety risk. • Contraceptive use by men and women must be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. • Subject is capable of giving signed informed consent.
Critères d'exclusion	• Subjects with active or untreated central nervous system (CNS) metastases and/or carcinomatous meningitis are not eligible. • Subjects who suffer from cardiovascular diseases of clinical significance. • Subjects with serious and/or uncontrolled concomitant diseases. • Subjects diagnosed active hepatitis B or hepatitis C. • Subjects have known human immunodeficiency virus (HIV) infection that is not well controlled. • Subjects with known active tuberculosis. • Known allergy or hypersensitivity to pembrolizumab or SKB264, or the excipients of pembrolizumab or SKB264. • Subjects with history of allogeneic tissue/solid organ transplant.

- Subjects previously treated with TROP2 targeted therapy.
- Subjects who are vaccinated with live vaccine within 30 days before the first dose, or plan to be vaccinated with live vaccine during the study period.
- Subjects participating in another clinical study, unless it is an observational (non-intervention) clinical study or the follow-up period of an intervention study.
- The Investigator considers other situations that will interfere with the evaluation of the study intervention or the safety of the subjects or the interpretation of the results of the study.