Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	An Open-label, Phase 2 Basket Study of SEA-CD40 Combination Therapies in Advanced Malignancies
Protocole ID	SGNS40-002 (KEYNOTE-C86)
ClinicalTrials.gov ID	NCT04993677
Type(s) de cancer	Mélanome Poumon non à petites cellules
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	SEA-CD40
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 Olivier Dumas
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Statut	Fermé
But étude	This trial is being done to see if an experimental drug (SEA-CD40) works when it's given with other cancer drugs to treat some types of cancer. It will also study side effects from the drug.There are 2 parts in this trial. In one part, participants have melanoma that has come back after treatment or can't be removed by surgery. Participants in this part will get SEA-CD40 and pembrolizumab. In the other part, participants have non-small cell lung cancer (NSCLC) that has spread through their body. These participants will get SEA-CD40, pembrolizumab, carboplatin, and pemetrexed.

Critères d'éligibilité	• Histologically or cytologically confirmed unresectable malignancy defined as one of the following:
	  • **Cohort 1: Relapsed and/or refractory metastatic melanoma**
	  • Uveal/ocular melanoma is excluded
	  • Must have progressed on treatment with an anti-PD-(L)1 mAb. PD-(L)1 treatment progression is defined as meeting all of the following criteria:
	  • Has received at least 2 doses of an approved anti-PD-(L)1 mAb
	  • Has demonstrated disease progression after PD-(L)1 as defined by RECIST v1.1.
	  • Progressive disease has been documented within 12 weeks from the last dose of anti- PD-(L)1 mAb
	  • Last dose of anti-PD-(L)1 must have been within 90 days prior to enrollment
	  • Participants with a targetable BRAF mutation must have been treated with, been intolerant of, or declined treatment with BRAF/MEK targeted therapy prior to study entry
	  • **Cohort 2: Metastatic uveal melanoma**
	  • Must not have received prior treatment for advanced or metastatic disease except for prior adjuvant/neoadjuvant immunotherapy
	  • No prior liver-directed therapy
	  • **Cohort 3: Metastatic PD-(L)1-naive melanoma**
	  • Uveal/ocular melanoma is excluded

	• Must not have received prior treatment for advanced or metastatic disease except for prior adjuvant/neoadjuvant immunotherapy. • For participants with a targetable BRAF mutation, prior BRAF/MEK targeted therapy is allowed if completed 4 weeks prior to first dose of study treatment. • **Cohorts 4 and 5: Non-squamous NSCLC** • Participants must have stage IV disease per AJCC 8th edition • No known driver mutations/alterations mutation for which targeted therapy is available • Must have non-squamous histology. • No prior therapy for metastatic disease • No prior treatment with anti-PD-(L)1 or PD-L2 agent or an antibody targeting other immuno-regulatory receptors or mechanisms • Able to provide archival tumor tissue from locations not radiated prior to biopsy. If archival tumor sample is not available a fresh baseline biopsy is required. • Eastern Cooperative Oncology Group (ECOG) Performance Status score of 0 or 1 • Measurable disease per RECIST v1.1 at baseline
Critères d'exclusion	• History of another malignancy within 3 years of first dose of study drug • Active central nervous system (CNS) metastases and/or carcinomatous meningitis. • Previous exposure to CD40-targeted therapy • Currently on chronic systemic steroids in excess of physiologic replacement • Has had an allogeneic tissue/solid organ transplant. • History of autoimmune disease that has required systemic treatment in the past 2 years