Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Phase 2 Study of Brentuximab Vedotin in Combination With Pembrolizumab in Subjects With Metastatic Solid Malignancies After Progression on Prior PD-1 Inhibitor Treatment
Protocole ID	SGN35-033 (KEYNOTE B81)
ClinicalTrials.gov ID	NCT04609566
Type(s) de cancer	Mélanome ORL Poumon non à petites cellules
Phase	Phase II
Stade	Métastatique
Type étude	Clinique
Médicament	Brentuximab védotine avec pembrolizumab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
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Statut	Fermé
Date d'activation	19-01-2023
But étude	This trial will find out whether brentuximab vedotin and pembrolizumab work together to treat different types of cancer. There will be several different types of cancer studied in the trial. The cancer must have spread to other parts of the body (metastatic)The study will also find out what side effects occur. A side effect is anything the treatment does besides treat cancer. This is a multi-cohort study.

Critères d'éligibilité	• Participants must have
	  • Metastatic squamous or nonsquamous non-small cell lung cancer (NSCLC) (without known targetable EGFR, ALK, ROS1, or BRAF mutations) who either
	  • a) have not yet received frontline therapy for metastatic disease and without prior exposure to anti PD-1/PD-L1 or
	  • b) are relapsed/refractory with progression on anti PD-1/PD therapy.
	  • Relapsed/refractory metastatic cutaneous melanoma (regardless of mutation status) with progression on a PD-1 inhibitor
	  • Metastatic head and neck squamous cell carcinoma (HNSCC) who have not yet received frontline therapy for metastatic disease and without prior exposure to a PD-1/PD-L1 inhibitor.
	• Cohorts 1-4 only: Melanoma participants must be currently on PD-1 checkpoint inhibitor (CPI) therapy (e.g. nivolumab or pembrolizumab) or had their last dose of PD-1 CPI containing therapy as the last previous line of therapy within 90 days prior to enrollment; PD-1 CPI therapy must be the immediate prior line of treatment.
	• Cohorts 1-4 only: Participants must have progressed on treatment with an anti-PD-1 monoclonal antibody (mAb) administered either as monotherapy, or in combination with other

	CPIs or other therapies. PD-1 treatment progression is defined by meeting all of the following criteria. • Have received at least 2 doses of an approved PD-1 inhibitor. • Have demonstrated disease progression (PD) after a PD-1 inhibitor as defined by RECIST v1.1. • Progressive disease has been documented within 90 days from the last dose of PD-1 inhibitor. • Participants with melanoma will need iRECIST confirmation of progression with a second assessment at least four weeks after the initial date of progressive disease • NSCLC participants on PD-1 inhibitor containing therapy for less than 90 days will need iRECIST confirmation of progression at least 4 weeks after the initial date of progressive disease • Tumor tissue sample obtained within 3 months prior to enrollment is required, and no systemic anticancer therapy given after the sample was obtained. • An Eastern Cooperative Oncology Group (ECOG) Performance Status score of equal or less than 1
Critères d'exclusion	• Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis. • Prior immunosuppressive chemotherapy, any immunotherapy other than a PD-1 inhibitor within 4 weeks of first study drug dose. • History of another malignancy within 3 years before the first dose of study drug or any evidence of residual disease from a previously diagnosed malignancy.