Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase II de type « plateforme », ouverte et à répartition aléatoire, évaluant l'efficacité et l'innocuité de nouvelles combinaisons de spartalizumab chez des patients atteints de mélanomes non résécables ou métastatiques ayant déjà été traités
Protocole ID	PLATforM
ClinicalTrials.gov ID	NCT03484923
Type(s) de cancer	Mélanome
Phase	Phase II
Stade	Métastatique
Type étude	Traitement
Médicament	Spartalizumab avec LAG525 vs avec Capmatinib vs avec Canakinumab
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	Montréal
Investigateur principal	Dr Wilson Miller
Coordonnateur	Amine Saad 514-340-8222 poste 24599
Statut	Fermé
But étude	The primary purpose of this study is to evaluate the efficacy of novel spartalizumab (PDR001) combinations in previously treated unresectable or metastatic melanoma
Critères d'éligibilité	• Histologically confirmed unresectable or metastatic stage IIIB/C/D or IV melanoma using AJCC edition 8 • Previously treated for unresectable or metastatic melanoma: • Subjects with V600BRAF wild-type disease must have received prior therapy with checkpoint inhibitor therapy (i.e. anti-PD-1/PD-L1 single-agent, or in combination with anti-CTLA-4) and must have had objective evidence of disease progression (i.e. RECIST v1.1) while on or after this therapy. • Disease progression on or after prior therapy must have occurred within 12 weeks prior to randomization in the study. • The last dose of prior therapy (anti-PD-1, anti-PD-L1 or anti-CTLA-4) must have been received more than 4 weeks prior to randomization. • Subjects with V600BRAF mutant disease must have received prior therapy with checkpoint inhibitor therapy (i.e. anti-PD-1/PD-L1 single-agent, or in combination with anti-CTLA-4) and must have had objective evidence of disease progression (i.e. RECIST v1.1) while on or after this therapy. Subjects must also have received prior therapy with a V600BRAF inhibitor, either as a single-agent or in combination with a MEK inhibitor. • Disease progression on or after prior therapy must have occurred within 12 weeks prior to randomization in the study. • The last dose of prior therapy must have been received more than 4 weeks (for anti-PD-1, anti-PD-L1 or anti-CTLA-4) or more than 2 weeks (for V600BRAF or MEK inhibitor) prior to randomization. • ECOG performance status 0-2 • At least one measurable lesion per RECIST v1.1 • At least one lesion, suitable for sequential mandatory tumor biopsies (screening and on-treatment) in accordance with the biopsy guidelines specified in protocol. The same lesion

	must be biopsied sequentially. • Screening tumor biopsy must fulfill the tissue quality criteria outlined in the protocol, as assessed by a local pathologist
Critères d'exclusion	• Subjects with uveal or mucosal melanoma • Presence of clinically active or unstable brain metastasis. Note: Subjects with unstable brain lesions who have been definitively treated with stereotactic radiation therapy, surgery or gamma knife therapy are eligible. • Subjects with brain lesions who are untreated (i.e. newly discovered brain lesions during screening) or received whole brain radiation must have documented stable disease as assessed by two consecutive assessments ≥ 4 weeks apart and have not required steroids for at least ≥ 4 weeks prior to randomization. • Use of any live vaccines against infectious diseases within 3 months before randomization. • Active infection requiring systemic antibiotic therapy at time of randomization. • Systemic chronic steroid therapy (? 10mg/day prednisone or equivalent) or any other immunosuppressive therapy administered within 7 days prior to randomization. Note: Local steroids such as topical, inhaled, nasal and ophthalmic steroids are allowed. • Active, known or suspected autoimmune disease or a documented history of autoimmune disease. Note: Subjects with vitiligo, controlled type I diabetes mellitus on stable insulin dose, residual autoimmune-related hypothyroidism only requiring hormone replacement or psoriasis not requiring systemic treatment are permitted. • Prior allogenic bone marrow or solid organ transplant • History of known hypersensitivity to any of the investigational drugs used in this study • Prior systemic therapy for unresectable or metastatic melanoma except anti-PD-1/PD-L1 single-agent or in combination with anti-CTLA-4, or V600BRAF and MEK inhibitors. • Medical history or current diagnosis of myocarditis • Cardiac Troponin T (TnT) level > 2 x ULN at screening