Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	A Randomised, Open-Label, Phase 2 Study of Ceralasertib Monotherapy and Ceralasertib Plus Durvalumab in Patients With Unresectable or Advanced Melanoma and Primary or Secondary Resistance to PD-(L)1 Inhibition
Protocole ID	MONETTE
ClinicalTrials.gov ID	NCT05061134
Type(s) de cancer	Mélanome
Phase	Phase II
Type étude	Clinique
Médicament	Ceralasertib monothérapie et ceralasertib + durvalumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Joël Claveau
Coordonnateur	Véronique Jobin 418-525-4444 poste 15780
Statut	Actif en recrutement
Date d'activation	03-11-2022
But étude	**Main study:** This is an open-label, phase 2 study that aims to evaluate the efficacy and safety/tolerability of ceralasertib, when administered as monotherapy and in combination with durvalumab in participants with unresectable or advanced melanoma and primary or secondary resistance to PD-(L)1 inhibition**Biopsy sub-study:** This is an open-label, non-randomised, sub-study planned in participants suitable for 3 mandatory biopsies. Serial tumour biopsies are mandated in participants recruited into the sub-study and will be taken at baseline during the screening period, during treatment with ceralasertib monotherapy and during the off-treatment period of ceralasertib monotherapy.
Critères d'éligibilité	• Participants must have a histologically or cytologically confirmed diagnosis of unresectable or metastatic melanoma of cutaneous, acral or mucosal subtype • Availability of an archival tumour sample and a fresh tumour biopsy taken at screening • Patient must have received at least 1 prior immunotherapy (anti-PD-(L)1 ± anti-CTLA-4 [Cytotoxic T-lymphocyte-associated protein 4]) for a minimum of 6 weeks and no more than 2 prior regimens in the metastatic setting. Patients must have confirmed progression during treatment with a PD-(L)1 inhibitor +/- a CTLA-4 inhibitor. • The interval between the last dose of anti-PD-(L)1, BRAF/MEK (B-Rapidly Accelerated Fibrosarcoma gene/mitogen-activated protein kinase gene) inhibitor and the first dose of the study regimen must be a minimum of 14 days • Measurable disease by RECIST 1.1. • Patients must have a life expectancy ≥3 months from proposed first dose date. • Biopsy Sub-study: Consent to the provision of 3 mandatory tumour biopsies.

Critères d'exclusion	• Patients must not have experienced a toxicity that led to permanent discontinuation of prior checkpoint inhibitors (CPI) treatment. • History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 3 years before the first dose of study treatment • Uveal melanoma • Must not have experienced a Grade ≥ 3 immune-related AE or an immune-related neurologic or ocular AE of any grade while receiving prior immunotherapy • History of symptomatic congestive heart failure, unstable angina pectoris, uncontrolled cardiac arrhythmia, which is symptomatic or requires treatment (CTCAE Grade 3), symptomatic or uncontrolled atrial fibrillation despite treatment, or asymptomatic sustained ventricular tachycardia. Patients with atrial fibrillation controlled by medication or arrhythmias controlled by pacemakers may be permitted upon discussion with the study clinical lead. • History of organ transplant that requires use of immunosuppressive medications • Inadequate bone marrow and impaired hepatic or renal function • Known active infection requiring systemic therapy, active hepatitis infection, positive hepatitis C virus antibody, hepatitis B virus (HBV) surface antigen or HBV core antibody (anti-HBc), at screening • Patients with confirmed COVID-19 infection by polymearse chain reaction test who have not made a full recovery.