Essai Clinique

Généré le 23 nov. 2024 à partir de https://geoq.info/fr/pub/essai-clinique-5193-pdf

Titre	IDE196 (darovasertib) en association avec le crizotinib en comparaison avec le traitement choisi par l'investigateur en première ligne dans le mélanome uvéal métastatique négatif pour l'HLA-A2
Protocole ID	IDE196-002
ClinicalTrials.gov ID	NCT05987332
Type(s) de cancer	Mélanome
Phase	Phase II-III
Stade	Métastatique
Type étude	Clinique
Médicament	Darovasertib avec crizotinib versus une thérapie au choix de l'investigateur
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Rahima Jamal
Coordonnateur	Chantal Gosselin 514-890-8000 poste 24892
Statut	Actif en recrutement
Date d'activation	29-04-2024
But étude	This is a Phase 2/3, multi-arm, multi-stage, open-label study of human leukocyte antigen (HLA)-A*02:01 negative participants with metastatic uveal melanoma (MUM) who will be randomized to receive either IDE196 + crizotinib or investigator's choice of treatment (pembrolizumab, ipilimumab + nivolumab, or dacarbazine).
Critères d'éligibilité	• Histological or cytological confirmed Metastatic Uveal Melanoma • HLA-A*02:01 negative • No prior systemic therapy in the metastatic or advanced setting, regional or liver-directed therapy, ablations or surgical resection of oligometastatic disease, or neoadjuvant or adjuvant therapy is allowed • Measurable disease per RECIST 1.1 • Able to be safely administered and absorb study therapy • ECOG performance status 0 or 1 • Life expectancy of ≥3 months • Adequate organ function
Critères d'exclusion	• Previous treatment with a PKC inhibitor (including prior treatment with IDE196), an inhibitor directly targeting MET, or an inhibitor directly targeting GNAQ/11 • Concurrent malignant disease • AEs from prior anti-cancer therapy that have not resolved to Grade ≤1 • Symptomatic or untreated central nervous system (CNS) metastases, or CNS metastases that require corticosteroids • Active HIV infection or Hep B/C • Active adrenal insufficiency, active colitis, or active inflammatory bowel disease • History of interstitial lung disease, active pneumonitis, or history of pneumonitis • Active infection requiring systemic antibiotic therapy • Use of hematopoietic colony-stimulating factors (CSF) prior to start of study drug • Females who are pregnant or breastfeeding

- History of severe hypersensitivity reactions (eg, anaphylaxis) to other biologic drugs or monoclonal antibodies
- Contraindication for treatment with investigator's choice therapies as per applicable labelling
- Has any other condition that may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the opinion of the investigator, would make the participant inappropriate for entry into the study