Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude de phase 2, de l'INCMGA00012 chez des participants atteints d'un carcinome à cellules de Merkel métastatique
Protocole ID	INCMGA 0012-201
ClinicalTrials.gov ID	NCT03599713
Type(s) de cancer	Peau
Phase	Phase II
Stade	Métastatique
Type étude	Traitement
Médicament	INCMGA00012
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Catalin Mihalcioiu
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Statut	Fermé
But étude	Le but de cette étude est d'évaluer l'activité clinique et l'innocuité de l'INCMGA00012 chez les participants atteints d'un carcinome métastatique à cellules de Merkel.
Critères d'éligibilité	• Signed informed consent. • Diagnosis of MCC with distant metastatic disease as a component of tumor burden and no more than 3 prior systemic treatments, inclusive of systemic adjuvant therapy. • Eastern Cooperative Oncology Group performance status of 0 to 1. • Measurable disease according to RECIST v1.1. • Availability of tumor tissue (fresh or archival) for central pathology review. • Willingness to avoid pregnancy or fathering children based on protocol-defined criteria.
Critères d'exclusion	• Prior programmed cell death protein 1 (PD-1) or programmed cell death ligand protein 1 (PD-L1)-directed therapy. • Treatment with anticancer drugs or participation in another interventional clinical study within 21 days before the first administration of study drug. • Has not recovered to ≤ Grade 1 or baseline from toxic effects of prior therapy (with the exceptions for anemia not requiring transfusion support and any grade of alopecia) and/or complications from prior surgical intervention within 7 days before starting study treatment. • Radiation therapy administered within 2 weeks of first dose of study treatment or radiation therapy in the thoracic region that is > 30 Gy within 6 months of the first dose of study treatment. • Known central nervous system (CNS) metastases and/or carcinomatous meningitis. • History of second malignancy within 3 years (with exceptions). • Laboratory values outside the protocol-defined range at screening. • Clinically significant pulmonary, cardiac, gastrointestinal or autoimmune disorders. • Active bacterial, fungal, or viral infections, including hepatitis A, B, and C. • Receipt of a live vaccine within 90 days of planned start of study therapy. • Current use of protocol-defined prohibited medication. • Known hypersensitivity to another monoclonal antibody that cannot be controlled with standard

measures (eg, antihistamines and corticosteroids).
- Inability or unlikely, in the opinion of the investigator, to comply with the Protocol requirements.
- Participant who is pregnant or breastfeeding.