Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Une étude d'immunothérapie expérimentale destinée à évaluer l'innocuité, la tolérabilité et l'efficacité d'anti-LAG-3 avec et sans anti-PD-1 dans le traitement des tumeurs solides.
Protocole ID	CA224-020
ClinicalTrials.gov ID	NCT01968109
Type(s) de cancer	Mélanome
Phase	Phase I-II
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	Québec
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Statut	Fermé
But étude	The purpose of the study is to assess the safety, tolerability and effectiveness of experimental medication BMS-986016 administered alone and in combination with nivolumab in patients with solid tumors that have spread and/or cannot be removed by surgery.The following tumor types are included in this study:Non-Small Cell Lung Cancer (NSCLC), gastric cancer, hepatocellular carcinoma, renal cell carcinoma, bladder cancer, squamous cell carcinoma of the head and neck, and melanoma, that have NOT previously been treated with immunotherapy. NSCLC and melanoma that HAVE previously been treated with immunotherapy.
Critères d'éligibilité	• For Dose escalation: subjects with cervical, ovarian, bladder and colorectal cancer (CRC), head and neck, gastric and hepatocellular cancer naive to immuno-oncology agents; 1st line melanoma and 1st line/2nd line NSCLC; Renal Cell Carcinoma naive to IO; NSCLC progressing while on or after therapy with anti-PD1/anti-PDL-1 and melanoma subjects progressed while-on or after treatment with anti-PD1 or anti-PDL1 with or without anti-CTLA-4. • For Dose Expansion: all of the above in escalation except for cervical, ovarian, and CRC • Progressed, or been intolerant to, at least one standard treatment regimen, except for subjects in 1st line cohorts. • ECOG performance status between 0 and 2 • At least 1 lesion with measurable disease at baseline • Availability of an existing tumor biopsy sample (and consent to allow pre-treatment tumor biopsy)
Critères d'exclusion	• Primary central nervous system (CNS) tumors or solid tumors with CNS metastases as the only site of active disease • Autoimmune disease • Encephalitis, meningitis, or uncontrolled seizures in the year prior to informed consent • Uncontrolled CNS metastases