Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	Étude multi-indications de phase Ib sur l'anétumab ravtansine (BAY94-9343) dans le traitement de patients atteints de tumeurs exprimant la mésothéline récidivantes ou au stade avancé
Protocole ID	15834
ClinicalTrials.gov ID	NCT03102320
Type(s) de cancer	Tumeurs solides
Phase	Phase I
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Anetumab Ravtansine (BAY94-9343)
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
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Statut	Fermé
But étude	The key purpose of the main part of the study is to assess efficacy and safety of anetumab ravtansine as monotherapy or combination therapy for mesothelin expressing advanced solid tumors.The main purpose of the safety lead-in (dose-finding) part of the study is to determine the safety and tolerability of anetumab ravtansine in combination with cisplatin and in combination with gemcitabine, and to determine the MTD of anetumab ravtansine in combination with cisplatin for mesothelin expressing advanced cholangiocarcinoma and in combination with gemcitabine for mesothelin expressing advanced adenocarcinoma of the pancreas.
Critères d'éligibilité	• Availability of tumor tissue for mesothelin expression testing • Histologically-confirmed, mesothelin-expressing metastatic or advanced non-metastatic disease (tumour type specific inclusion criteria) • At least one measurable lesion according to either Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 or International Thymic Malignancy Interest Group (ITMIG) modified RECIST 1.1 as applicable • Adequate bone marrow, liver, renal and coagulation function • Left ventricular ejection fraction (LVEF) ≥ 50% of the lower limit of normal (LLN) according to local institutional ranges • Eastern Cooperative Oncology Group (ECOG) 0 or 1
Critères d'exclusion	• More than one prior anti-tubulin/microtubule agent • Corneal epitheliopathy or any eye disorder that may predispose the patients to this condition • Symptomatic Central nervous system (CNS) metastases and/or carcinomatous meningitis • Contraindication to both CT and MRI contrast agents • Active hepatitis B or C infection • Pregnant or breast-feeding patients • Tumor type specific exclusion criteria