Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Multicenter, Open-label, Phase 1b/2 Study To Evaluate Safety And Efficacy Of Avelumab (msb0010718c) In Combination With Chemotherapy With Or Without Other Anti-cancer Immunotherapies As First-line Treatment In Patients With Advanced Malignancies
Protocole ID	B9991023
ClinicalTrials.gov ID	NCT03317496
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase I
Type étude	Traitement
Médicament	Avelumab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	Montréal
Investigateur principal	Dr Scott Owen
Coordonnateur	Olivier Bouchereau 514-934-1934 poste 43129
Statut	Actif en recrutement
But étude	This is a Phase 1b/2, open label, multicenter, safety and clinical activity study of avelumab in combination with chemotherapy as first-line treatment of adult patients with locally advanced or metastatic solid tumors. Initially, avelumab will be evaluated in combination with pemetrexed and carboplatin in patients with advanced non-squamous non-small cell lung cancer (NSCLC) (Cohort A1) and in combination with gemcitabine and cisplatin in patients with cisplatin-eligible urothelial (bladder) cancer (UC) (Cohort A2). As more information is learned about other anti-cancer immunotherapy agents, in future portions of the study, avelumab may be combined with chemotherapy and other anti-cancer immunotherapy agents in patients with these same or different tumor types.
Critères d'éligibilité	• Histological diagnosis of locally advanced (primary or recurrent) or metastatic solid tumor that is not amenable for treatment with curative intent as follows: • For all groups: • Measurable disease by RECIST v1.1 with at least 1 measurable lesion; • No prior systemic treatment for unresectable locally advanced or metastatic disease for the tumor type under study. If prior systemic chemotherapy treatment was given in the adjuvant or neo-adjuvant setting or as part of radiotherapy chemotherapy treatment, disease-free interval after stop of systemic treatment must be more than 6 months for non-squamous NSCLC and more than 12 months for UC; • Cohort A1: Non-squamous NSCLC, with no activating EGFR mutations, ALK or ROS1 translocations/rearrangements. If monotherapy pembrolizumab is available as a standard of care treatment option, patients must have a tumor proportion score (TPS) <50% for PD L1 (via the 22C3 pharmDx or the Ventana (SP263) PD L1 IHC assay). • Cohort A2: Transitional cell carcinoma of the urothelium including the bladder, urethra, renal pelvis, and ureter. • ECOG performance status 0 or 1 • Estimated life expectancy of at least 90 days • Adequate bone marrow, renal, and liver function • Negative serum pregnancy test at screening • Male and female patients able to have children must agree to use 2 highly effective methods of contraception throughout the study and for at least 90 days after last dose of chemotherapy or at least 30 days after last dose of avelumab, whichever is longer

	• Signed and dated informed consent
Critères d'exclusion	• Prior immunotherapy with any antibody or drug specifically targeting T cell co-stimulation or immune checkpoint pathways. • Patients with known symptomatic central nervous system metastases requiring steroids. • Diagnosis of other malignancy within 2 years prior to enrollment except adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ of the bladder, breast, or cervix, or low grade (Gleason ≤6) prostate cancer • Use of immunosuppressive medication at the time of enrollment • Active or prior autoimmune disease that might deteriorate when receiving an immuno-stimulatory agent. • Prior organ transplantation including allogenic stem cell transplantation • Active infection requiring systemic therapy • Known history of HIV or AIDS • Hepatitis B virus (HBV) or hepatitis C virus (HCV) infection at screening • Administration of live vaccine within 4 weeks prior to study entry • Known prior severe hypersensitivity to the investigational products or any component in their formulations, • Known prior severe hypersensitivity to platinum-related compounds for all cohorts, to pemetrexed for patients enrolled in Cohort A1, and to gemcitabine for patients enrolled in Cohort A2 • Persisting toxicity related to prior therapy (NCI CTCAE v4.03 Grade > 1) • Known history of colitis, inflammatory bowel disease, pneumonitis, pulmonary fibrosis. • Ongoing cardiac dysrhythmias of NCI CTCAE v4.03 Grade 2 or prolongation of the QTcF interval to >480 msec. • Clinically significant (ie, active) cardiovascular disease: cerebral vascular accident/stroke (<6 months prior to enrollment), myocardial infarction (< 6 months prior to enrollment), unstable angina, congestive heart failure, or serious cardiac arrhythmia requiring medication. • Major surgery ≤28 days or major radiation therapy ≤14 days prior to enrollment. • Participation in other studies involving investigational drug(s) within 28 days prior to study entry. • Concurrent treatment with a prohibited medication. • Other acute or chronic medical or psychiatric condition • Pregnant female patients; breastfeeding female patients; fertile male patients and female patients of childbearing potential who are unwilling or unable to use 2 highly effective methods of contraception as outlined in this protocol for the duration of the study and for at least 90 days after the last dose of chemotherapy or at least 30 days after the last dose of avelumab, whichever is longer.