Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Étude de phase I/II sur l'ALKS 4230 administré par voie sous-cutanée en monothérapie et en association avec le pembrolizumab chez des sujets atteints de tumeurs solides avancées
Protocole ID	ARTISTRY-2
ClinicalTrials.gov ID	NCT03861793
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	ALKS 4230 en monothérapie et en association avec le pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL L'HOTEL-DIEU DE QUEBEC ET CRCEO 11 Côte du Palais, Québec, QC, G1R 2J6
Ville	
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Statut	Fermé
But étude	This study will characterize the safety and tolerability and identify the recommended Phase 2 dose (RP2D) of subcutaneous (SC) ALKS 4230 as monotherapy and in combination with pembrolizumab.
Critères d'éligibilité	• For Part A the subject has histological or cytological evidence of a solid tumor. For Part B the subject must have 1 of the unspecified adult solid tumor types defined in the protocol • Record of programmed cell death ligand 1 protein expression status, or availability of fresh or archival tumor tissue for cellular characterization and PD-L1 status • Subjects must have adequate liver function • Subjects must have adequate kidney function • Subjects must be recovered from the effects of any prior chemotherapy, immunotherapy, other prior systemic anticancer therapy, radiotherapy or surgery • Subjects who have received radiation therapy must wait at least 4 weeks after their last radiation treatment before enrollment into the study • Females of childbearing potential must have a negative pregnancy test within 7 days of the start of treatment and on Day 1 before the first dose is administered • Subject will agree to follow contraceptive requirements defined in the protocol • Additional criteria may apply
Critères d'exclusion	• Subject is currently pregnant, planning to become pregnant, or breastfeeding • Subjects with an active infection or with a fever ≥ 38.5°C within 3 days of the first scheduled day of dosing for Cycle 1 • Subjects with active or symptomatic central nervous system metastases are excluded. Subjects with central nervous system metastases are eligible for the study if the metastases have been treated by surgery and/or radiation therapy, the subject is off corticosteroids for at least 2 weeks, and the subject is neurologically stable • Subjects with known hypersensitivity to any components of ALKS 4230 or to pembrolizumab or any of its excipients • Subjects who require pharmacologic doses of steroids; replacement doses, topical,

ophthalmologic, and inhalational steroids are permitted
- Subjects who developed autoimmune disorders while on prior immunotherapy, including pneumonitis, nephritis, and/or neuropathy
- Subjects with any other concurrent uncontrolled illness, including mental illness or substance abuse, which may interfere with the ability of the subjects to cooperate and participate in the study
- The subject is known to be positive for human immunodeficiency virus (HIV), hepatitis B or C, or active tuberculosis, or has a known history of tuberculosis
- Additional criteria may apply