Essai Clinique

Généré le 29 avr. 2024 à partir de

Titre	A Phase 1/2 Study of ALKS 4230 Administered Intravenously as Monotherapy and in Combination With Pembrolizumab in Subjects With Advanced Solid Tumors
Protocole ID	ARTISTRY-1
ClinicalTrials.gov ID	NCT02799095
Type(s) de cancer	Tumeurs solides
Phase	Phase I-II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	ALKS 4230 IV 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	
Investigateur principal	Dr Olivier Dumas
Coordonnateur	Maryse Gingras 418-691-5781
Statut	Actif en recrutement
But étude	To investigate the safety and tolerability of ALKS 4230, determine the recommended Phase 2 dose (RP2D) and assess anti-tumor activity in Monotherapy and ALKS 4230 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 has a diagnosis of melanoma or renal cell carcinoma • All subjects must have advanced solid tumors that have returned after treatment with established approved therapies or be intolerant of established therapies • Subjects enrolled in Part B or Part C must have at least 1 lesion that may qualify as a target lesion • Subject can move around on their own, has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, and has an estimated life expectancy of at least 3 months • Subject must have adequate hematologic reserve • 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 investigational agents must wait at least 4 weeks • 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. A female not of childbearing potential is one who has undergone bilateral oophorectomies or who is postmenopausal, defined as >45 years of age and without a menstrual period for 12 consecutive months • Meets contraceptive requirements defined in the protocol • Additional criteria may apply

Critères d'exclusion	• Subject is currently pregnant or breastfeeding, or is planning to become pregnant during the study • Subjects with an active infection or with a fever >/= 38.5 degrees 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 have a mean QT interval corrected by the Fridericia Correction formula value of >470 msec (in females) or >450 msec (in males) • Subjects with known hypersensitivity to any components of ALKS 4230 • Subjects with known hypersensitivity to any components of pembrolizumab (for patients in combination arm only) • Subjects who require pharmacologic doses of corticosteroids; replacement doses, topical, ophthalmologic, and inhalational steroids are permitted • Subjects who developed autoimmune disorders while on prior immunotherapy, including pneumonitis, nephritis, and neuropathy • Subjects with any other concurrent uncontrolled illness, including mental illness or substance abuse, which may interfere with the ability of the subject 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 • Subjects with dyspnea at rest of requiring oxygen therapy • Subjects active autoimmune disease requiring systemic treatment within the past 30 days • Subjects who received radiotherapy within the last 4 weeks before start of study treatment administration with the exception of limited field palliative radiotherapy • Subjects who have received systemic immunomodulatory agents within 28 days prior to C1D1. • Subjects who have received administration of a live, attenuated vaccine within 4 weeks of Cycle 1, Day1. • Prior solid organ and/or non-autologous hematopoietic stem cell or bone marrow transplant recipients • Subjects who have received prior IL-2 based or IL-15 based cytokine therapy • Additional criteria may apply