Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	A Phase 2, Open-label, Multicenter, Cohort Study of Nemvaleukin Alfa (ALKS 4230) Monotherapy Administered Subcutaneously in Patients With Advanced Cutaneous Melanoma or Intravenously in Patients With Advanced Mucosal Melanoma Who Have Previously Received Anti-PD-[L]-1 Therapy
Protocole ID	ARTISTRY-6
ClinicalTrials.gov ID	NCT04830124
Type(s) de cancer	Mélanome
Phase	Phase II
Type étude	Clinique
Médicament	Nemvaleukin Alfa
Institution	CENTRE HOSPITALIER DE L'UNIVERSITE DE MONTREAL
Ville	
Investigateur principal	Dre Rahima Jamal
Coordonnateur	Samantha Gennevois 514-890-800 poste 31523
Statut	Actif en recrutement
But étude	This study observes the antitumor activity, safety, tolerability, PK, and pharmacodynamics in patients with inoperable and/or metastatic melanoma following prior anti-PD-[L]-1 therapy

Critères d'éligibilité	• The patient must have advanced cutaneous melanoma or acral melanoma; no more than 5 patients with acral melanoma may enroll in this cohort (Cohort 1). Or, the patient must have unresectable and/or metastatic mucosal melanoma (Cohort 2).
	• The patient must have received previous treatment as follows:
	  • Patient has received anti-PD-[L]1 therapy with or without anti-CTLA-4 therapy, and no more than one other prior regimen of systemic anti-neoplastic therapy (eg, targeted therapy, chemotherapy). Previous adjuvant and/or neoadjuvant therapy counts as one prior regimen.
	  • Patients have experienced objective response (partial response [PR] or CR; by RECIST 1.1 or iRECIST) or stable disease (SD; by RECIST 1.1 or iRECIST) as best overall response (BOR) to anti-PD-[L]1 therapy. Patients with confirmed progressive disease (by RECIST 1.1 or iRECIST) as best response may be included, if they received anti-PD-[L]1 therapy for a minimum of 12 weeks (eg, 4 doses of pembrolizumab every 3 weeks).
	  • Patients with BRAF mutations may or may not have received prior targeted therapy.
	• Patients must have disease that is measurable based on RECIST 1.1., that has not recently been irradiated or used to collect a biopsy.
	• Patient is willing to undergo a pretreatment tumor biopsy or provide qualifying archival tumor tissue.
	• Patient has an Eastern Cooperative Oncology Group (ECOG) status of 0 or 1 and an estimated life expectancy of ≥3 months.
	• Additional criteria may apply.

Critères d'exclusion	• Patient has uveal melanoma. • Patient has received prior IL-2-based or IL-15-based cytokine therapy; patient has had exposure, including intralesional, to IL-12 or analogs thereof. • Patient requires systemic corticosteroids (>10 mg of prednisone daily, or equivalent) however, replacement doses, topical, ophthalmologic, and inhalational steroids are permitted. • Patient has undergone prior solid organ and/or non-autologous hematopoietic stem cell or bone marrow transplant. • Patient is currently pregnant, breastfeeding, or is planning to become pregnant or to begin breastfeeding during the study period or within 30 days after last study drug administration. • Patients with active or symptomatic central nervous system metastases unless the metastases have been treated by surgery and/or radiation therapy and/or gamma knife, the subject has been tapered to a dose of 10 mg of prednisone (or equivalent) or less of corticosteroids for at least 2 weeks before the first dose, and the subject is neurologically stable. Patients with leptomeningeal disease are excluded. • Patient has known or suspected hypersensitivity to any components of nemvaleukin. • Patients with an uncontrollable bleeding disorder. • Patient has QT interval corrected by the Fridericia Correction Formula values of >470 msec (in females) or >450 msec (in males); patient who is known to have congenital prolonged QT syndromes; or patient who is on medications known to cause prolonged QT interval on ECG. • Patient has developed Grade ≥3 immune-related AEs (irAEs) while on prior immunotherapy, (eg, pneumonitis, nephritis, and neuropathy). • Additional criteria may apply.