Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	A Phase 3, Randomized, Open-label, Study of Subcutaneous Nivolumab + Relatlimab Fixed-dose Combination Versus Intravenous Nivolumab + Relatlimab Fixed-dose Combination in Participants With Previously Untreated Metastatic or Unresectable Melanoma
Protocole ID	RELATIVITY-127 (CA224-127)
ClinicalTrials.gov ID	NCT05625399
Type(s) de cancer	Mélanome
Phase	Phase III
Type étude	Clinique
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Félix Couture
Coordonnateur	Maryse Gingras 418-691-5781
Statut	Fermé
Date d'activation	15-05-2023
But étude	The purpose of this study is to demonstrate that the study drug exposure level of the nivolumab + relatlimab FDC subcutaneous (SC) formulation is not worse than nivolumab + relatlimab FDC intravenous (IV) administration in participants with previously untreated metastatic or unresectable melanoma.
Critères d'éligibilité	• Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1/Lansky Performance Score ≥ 80% for adolescents (≥ 12 to < 18 years of age). • Participants must have histologically confirmed Stage III (unresectable) or Stage IV (metastatic) melanoma, per the American Joint Committee for Cancer (AJCC) staging system. • Participants must have measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1). • Participants must be ≥ 12 years of age. Participants who are ≥ 12 years of age and < 18 years of age (adolescents) must weigh ≥ 40 kg at the time of signing the informed consent (assent). • Participants must have histologically confirmed Stage III (unresectable) or Stage IV (metastatic) melanoma, per the AJCC staging system (8th edition).
Critères d'exclusion	• Participants must not have ocular melanoma. • Participants must not have a history of myocarditis, regardless of etiology. • Participants must not have a condition requiring systemic treatment with either corticosteroids (>10 milligrams [mg] daily prednisone equivalent) or other immunosuppressive medications within 14 days of start of study treatment. Inhaled or topical steroids, and adrenal replacement steroid doses >10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease.