




Essai Clinique

Généré le 16 mai 2024 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
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Statut	Actif en recrutement
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	<ul style="list-style-type: none">• Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1/Lansky Performance Score $\geq 80\%$ 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	<ul style="list-style-type: none">• 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.