Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	A Phase 3, Randomized, Double-blind Study of Adjuvant Immunotherapy With Relatlimab and Nivolumab Fixed-dose Combination Versus Nivolumab Monotherapy After Complete Resection of Stage III-IV Melanoma
Protocole ID	RELATIVITY-098 (CA224-098)
ClinicalTrials.gov ID	NCT05002569
Type(s) de cancer	Mélanome
Phase	Phase III
Type étude	Clinique
Médicament	Relatlimab et nivolumab versus nivolumab monothérapie
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 Maxime Chénard-Poirier
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Statut	Fermé
Date d'activation	10-06-2022
But étude	The purpose of this study is to assess relatlimab and nivolumab fixed-dose combination (FDC) versus nivolumab alone in participants with completely resected stage III-IV melanoma.
Critères d'éligibilité	• Must have been diagnosed with either Stage IIIA (> 1 mm tumor in lymph node)/B/C/D or Stage IV melanoma by American Joint Committee on Cancer (AJCC) v8 and have histologically confirmed melanoma that is completely surgically resected (free of disease) with negative margins in order to be eligible • Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 • Complete resection must be performed within 12 weeks prior to randomization • All participants must have disease-free status documented by a complete physical examination within 14 days prior to randomization and imaging studies within 35 days prior to randomization • Tumor tissue must be provided for biomarker analyses
Critères d'exclusion	• History of uveal melanoma • Untreated/unresected CNS metastases or leptomeningeal metastases • Active, known, or suspected autoimmune disease • Participants with serious or uncontrolled medical disorder • Prior immunotherapy treatment for any prior malignancy: No prior immunotherapies are permitted • Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection 4 weeks prior to screening Other protocol-defined inclusion/exclusion criteria apply