Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Randomized, Double-Blind, Parallel, Phase 1 Study to Compare the Pharmacokinetics of BMSCHO1-Nivolumab Process D to Nivolumab Process C After Complete Resection of Stage IIIa/b/c/d or Stage IV Melanoma
Protocole ID	CA209-8FC
ClinicalTrials.gov ID	NCT03980314
Type(s) de cancer	Mélanome
Phase	Phase I
Type étude	Traitement
Médicament	Nivolumab
Institution	CISSS DE LA MONTEREGIE-CENTRE HOPITAL CHARLES-LE MOYNE 3120 boulevard Taschereau, Greenfield Park, QC, J4V2H1
Ville	
Investigateur principal	Dre Céline Devaux
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Statut	Fermé
But étude	The study is intended to compare the pharmacokinetic of Process D nivolumab to Process C nivolumab administered after complete resection of Stage IIIa/b/c/d or Stage IV melanoma.
Critères d'éligibilité	• Late Stage melanoma that is completely surgically resected and pathologically absent • Participants must not have received anti-cancer therapy greater than equal to (>=) 6 months prior to randomization • Imaging studies to include Computed tomography (CT), Magnetic resonance imaging (MRI), positron emission tomography (PET) scans that show no clinically detectable nodes on imaging
Critères d'exclusion	• Participants must not have a history of ocular/uveal melanoma • Participants with active, known, or suspected autoimmune disease(s) not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger are permitted to enroll • Participants must not have prior malignancy active within the previous 3 years except for locally curable cancers • Participants must not have a condition requiring systemic treatment with either corticosteroids or other immunosuppressive medications within 14 days of study drug administration. • Participants must not have had prior therapy for melanoma except surgery, for the melanoma lesion(s) adjuvant radiation therapy after neurosurgical resection for CNS lesions and except for participants who received prior adjuvant interferon therapy • Treatment directed against the resected melanoma that is administered after complete resection other than adjuvant radiation