



Essai Clinique

Généré le 13 mai 2025 à partir de

Titre	A Phase Ib, Open-Label, Multicenter Study to Evaluate the Safety, Pharmacokinetics, and Activity of Belvarafenib as a Single Agent and in Combination With Either Cobimetinib or Cobimetinib Plus Atezolizumab in Patients With NRAS-Mutant Advanced Melanoma Who Have Received Anti-PD-1/PD-L1 Therapy
Protocole ID	GO42273
ClinicalTrials.gov ID	NCT04835805
Type(s) de cancer	Mélanome
Phase	Phase I
Type étude	Clinique
Médicament	Belvarafenib seul et en combinaison avec cobimetinib ou cobimetinib plus atézolizumab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
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Investigateur principal	Dr Wilson Miller
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Statut	Fermé
But étude	This study will evaluate the safety, pharmacokinetics, and activity of belvarafenib as a single agent and in combination with either cobimetinib or cobimetinib plus atezolizumab in patients with NRAS-mutant advanced melanoma who have received anti-PD-1/PD-L1 therapy.
Critères d'éligibilité	<ul style="list-style-type: none">• ECOG Performance Status of 0 or 1• Histologically confirmed, metastatic (recurrent or de novo Stage IV) or unresectable locally advanced (Stage III) cutaneous melanoma, that has progressed on or after treatment with anti-PD-1 or anti-PD-L1 therapy. Patients may have received up to two lines of systemic cancer therapy. Treatment with anti-PD-1/PD-L1 in the adjuvant setting is acceptable. Patients must have progressive disease at study entry• Documentation of NRAS mutation-positive within 5 years prior to screening• Tumor specimen availability• Adequate hematologic and end-organ function• Measurable disease per RECIST v1.1
Critères d'exclusion	<ul style="list-style-type: none">• Treatment with systemic immunotherapy agents (e.g., anti-CTLA4, anti-PD(L)1, cytokine therapy, investigational therapy, etc.) within 28 days prior to C1D1• Symptomatic, untreated, or actively progressing CNS metastases• History or signs/symptoms of clinically significant cardiovascular disease• Known clinically significant liver disease• History of autoimmune disease or immune deficiency• Prior treatment with a MEK inhibitor (cobimetinib arm)• History of or evidence of retinal pathology on ophthalmologic examination (cobimetinib arm)• History of immune-related AE attributed to prior anti-PD(L)1 therapy that resulted in permanent discontinuation of anti-PD(L)1 therapy (atezolizumab arm)