




Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	Étude clinique de phase 3, randomisée, à double insu, contrôlée par placebo et comparateur actif, portant sur le V940 (ARNm-4157) adjuvant et le pembrolizumab par rapport au placebo adjuvant et au pembrolizumab chez des participants atteints d'un mélanome de stade II à IV à haut risque
Protocole ID	V940-001
ClinicalTrials.gov ID	NCT05933577
Type(s) de cancer	Mélanome
Phase	Phase III
Type étude	Clinique
Médicament	V940 + pembrolizumab versus placebo + pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL  HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Joël Claveau
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Statut	Actif en recrutement
Date d'activation	13-10-2023
But étude	The purpose of this study is to learn if V940 which is an individualized neoantigen therapy (INT; formerly, called messenger ribonucleic acid [mRNA]-4157) with pembrolizumab (MK-3475) is safe and prevents cancer from returning in people with high-risk melanoma. Researchers want to know if V940 with pembrolizumab is better than receiving pembrolizumab alone at preventing the cancer from returning.
Critères d'éligibilité	The main inclusion criteria include but are not limited to the following: <ul style="list-style-type: none">• Has surgically resected and histologically/pathologically confirmed diagnosis of Stage IIB or IIC, III, or IV cutaneous melanoma• Has not received any prior systemic therapy for their melanoma beyond surgical resection• No more than 13 weeks have passed between final surgical resection and the first dose of pembrolizumab• Is disease free at the time of providing documented consent for the study• Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on anti-retroviral therapy (ART)
Critères d'exclusion	The main exclusion criteria include but are not limited to the following: <ul style="list-style-type: none">• Has ocular or mucosal melanoma• Has past or current cancer that has spread to other parts of the body• Has heart failure within the past 6 months• Has received prior cancer therapy or another cancer vaccine• Has another known cancer that that has spread to other parts of the body or has required treatment within the past 3 years• Has severe reaction to study medications or any of their substance used to prepare a drug• Have not recovered from major surgery or have ongoing surgical complications