



Essai Clinique

Généré le 17 mai 2024 à partir de

Titre	A Phase III, Randomized, Open-Label, Multicenter, Global Study of Volrustomig (MEDI5752) in Combination With Carboplatin Plus Pemetrexed Versus Platinum Plus Pemetrexed or Nivolumab Plus Ipilimumab in Participants With Unresectable Pleural Mesothelioma
Protocole ID	eVOLVE-Meso
ClinicalTrials.gov ID	NCT06097728
Type(s) de cancer	Mésothéliome
Phase	Phase III
Type étude	Clinique
Médicament	Volrustomig + carboplatine + pemetrexed versus un platine + pemetrexed ou nivolumab + ipilimumab
Institution	INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUEBEC - UL
Ville	
Investigateur principal	Dre Catherine Labbé
Coordonnateur	Brigitte Fortin 418-656-8711 poste 2639
Statut	Actif en recrutement
Date d'activation	23-11-2023
But étude	This is a phase III, randomized, open-label, multicenter, global study to determine the efficacy and safety of Volrustomig (MEDI5752) + Carboplatin + Pemetrexed vs the investigator's choice of platinum + Pemetrexed or Nivolumab + Ipilimumab in participants with unresectable pleural mesothelioma.
Critères d'éligibilité	• Participant must be ≥ 18 years at the time of screening • Histologically proven diagnosis of pleural mesothelioma with known histology (epithelioid vs. non-epithelioid) • Advanced unresectable disease that cannot be treated with curative surgery (with or without chemotherapy) • WHO/ECOG performance status of 0 or 1 with no deterioration (that is, ECOG PS>1) over the previous 2 weeks prior to day of first dosing • Has measurable disease per modified RECIST1.1 • Has adequate bone marrow reserve and organ function at baseline
Critères d'exclusion	• As judged by the investigator, any condition that would interfere with evaluation of the investigational product or interpretation of participant safety or study results. • Active or prior documented autoimmune or inflammatory disorders • History of another primary malignancy with exceptions. • Uncontrolled intercurrent illness • Tuberculosis, hepatitis B (HBV) or hepatitis C (HCV), human immunodeficiency virus (HIV) infection that is not well controlled • Any concurrent chemotherapy, radiotherapy, investigational, biologic, or hormonal therapy for cancer treatment • Untreated or progressive CNS metastatic disease