Essai Clinique

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Titre	A Randomized Phase 3 Study of the Combination of Pembrolizumab Plus Epacadostat Alone or With Platinum-based Chemotherapy Versus Pembrolizumab Plus Platinum-based Chemotherapy Plus Placebo as First-Line Treatment in Patients With Metastatic Non-Small Cell Lung Cancer
Protocole ID	MK-3475-715/KEYNOTE-715-05
ClinicalTrials.gov ID	NCT03322566
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Métastatique
Type étude	Traitement
Médicament	Epacadostat, Pembrolizumab, Chimio
Institution	CIUSSS DE L'OUEST-DE-L'ILE-DE-MONTREAL CENTRE HOSPITALIER DE ST. MARY 3830 av. Lacombe, Montréal, QC, H3T 1M5
Ville	Montreal
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Statut	Fermé
But étude	The purpose of this study is to evaluate the efficacy and safety of pembrolizumab plus epacadostat alone or with platinum-based chemotherapy versus pembrolizumab plus platinum-based chemotherapy plus placebo as first-line therapy in participants with metastatic non-small cell lung cancer (NSCLC).
Critères d'éligibilité	• Histologically or cytologically confirmed diagnosis of stage IV NSCLC without epidermal growth factor receptor (EGFR)-sensitizing mutation, ROS1 and/or anaplastic lymphoma kinase (ALK) translocation • Measurable disease based on RECIST 1.1 • Life expectancy of at least 3 months. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • Adequate organ function per protocol-defined criteria. • Provide tumor tissue sample.
Critères d'exclusion	• Known untreated central nervous system metastases and/or carcinomatous meningitis • History of (non-infectious) pneumonitis that required systemic steroids or current pneumonitis/interstitial lung disease. • Symptomatic ascites or pleural effusion. • Known history of an additional malignancy, except if the participant has undergone potentially curative therapy with no evidence of that disease recurrence for 5 years since initiation of that therapy. • Active autoimmune disease that has required systemic treatment in past 2 years. • Has had an allogeneic tissue/solid organ transplant. • Has a known history of human immunodeficiency virus (HIV) infection. HIV testing is not required unless mandated by the local health authority. • Has known history of or is positive for active Hepatitis B (HBsAg reactive) or has active Hepatitis C (HCV RNA). Note: Testing must be performed to determine eligibility. • History or presence of an abnormal electrocardiogram (ECG) that, in the Investigator's opinion,

is clinically meaningful.
- Use of protocol-defined prior/concomitant therapy.