Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	Essai de phase III à répartition aléatoire et à double insu sur l'emploi d'une bichimiothérapie à base de platine avec ou sans pembrolizumab (MK-3475) comme traitement néoadjuvant ou adjuvant chez les participants atteints d'un CPNPC résécable de stade IIB ou IIIA
Protocole ID	MK-3475-671
ClinicalTrials.gov ID	NCT03425643
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Type étude	Traitement
Médicament	Pembrolizumab
Institution	CIUSSS DE L'OUEST-DE-L'ILE-DE-MONTREAL CENTRE HOSPITALIER DE ST. MARY 3830 av. Lacombe, Montréal, QC, H3T 1M5
Ville	Montréal
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Statut	Fermé
But étude	This trial will evaluate the safety and efficacy of pembrolizumab (MK-3475) in combination with platinum doublet neoadjuvant chemotherapy (NAC) before surgery [neoadjuvant phase], followed by pembrolizumab alone after surgery [adjuvant phase] in participants with resectable stage IIB or IIIA non-small cell lung cancer (NSCLC). The primary hypotheses of this study are that neoadjuvant pembrolizumab (vs. placebo) in combination with NAC, followed by surgery and adjuvant pembrolizumab (vs. placebo) will improve: 1) event free survival (EFS) by biopsy assessed by blinded central pathologist or by imaging using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) assessed by blinded independent central review (BICR); and 2) overall survival (OS).
Critères d'éligibilité	• Have previously untreated, histologically confirmed NSCLC and histologically confirmed Stage IIB or IIIA NSCLC. • Be able to undergo protocol therapy, including necessary surgery. • If male, must agree to use contraception or practice abstinence as well as refrain from donating sperm for at least 180 days after the last dose of study treatment. • If female, may participate if not pregnant, not breastfeeding, and at least one of the following conditions apply: 1) not a woman of childbearing potential (WOCBP); or 2) a WOCBP who agrees to follow contraceptive guidance during the treatment period and for at least 180 days after the last dose of study treatment. • Have available formalin-fixed paraffin embedded (FFPE) tumor tissue sample blocks for submission. If blocks are not available, have unstained slides for submission for central programmed death-ligand 1 (PD-L1) testing. • Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 10 days of randomization. • Have adequate organ function.

Critères d'exclusion	• A WOCBP who has a positive urine pregnancy test within 24 hours before the first dose of study treatment. • Has one of the following tumor locations/types:1) NSCLC involving the superior sulcus; 2) Large cell neuro-endocrine cancer (LCNEC); or 3) Sarcomatoid tumor. • Has a history of (non-infectious) pneumonitis /interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease that requires steroids. • Has an active infection requiring systemic therapy. • Has had an allogenic tissue/sold organ transplant. • Has a known severe hypersensitivity (≥ Grade 3) to pembrolizumab, its active substance and/or any of its excipients. • Has a known severe hypersensitivity (≥ Grade 3) to any of the study chemotherapy agents and/or to any of their excipients. • Has an active autoimmune disease that has required systemic treatment in past 2 years. • Has a known history of human immunodeficiency virus (HIV) infection. • Has a known history of Hepatitis B or Hepatitis C. • Has a known history of active tuberculosis. • Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the trial, interfere with the participant's participation for the full duration of the trial, or is not in the best interest of the participant to participate. • Has known psychiatric or substance abuse disorders that would interfere with cooperating with the requirements of the trial. • Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another co-inhibitory T-cell receptor. • Has received prior systemic anti-cancer therapy including investigational agents for the current malignancy prior to randomization/allocation. • Has received prior radiotherapy within 2 weeks of start of trial treatment. • Has received a live vaccine within 30 days prior to the first dose of trial drug. • Is currently participating in or has participated in a trial of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of trial treatment. • Has a diagnosis of immunodeficiency or is receiving either systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of trial drug. • Has a known additional malignancy that is progressing or requires active treatment within the past 5 years. • Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the trial, starting with the screening visit through 180 days after the last dose of trial treatment.