Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Phase 3 Randomized Clinical Study of MK-4280A (Coformulated Favezelimab [MK-4280] Plus Pembrolizumab [MK-3475]) Versus Physician's Choice Chemotherapy in PD-(L)1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma
Protocole ID	KEYFORM-008 (MK-4280A-008)
ClinicalTrials.gov ID	NCT05508867
Type(s) de cancer	Hodgkin (Maladie de)
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Favezelimab/?Pembrolizumab versus une chimiothérapie au choix de l'investigateur
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
Ville	
Investigateur principal	Dre Nathalie Johnson
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Statut	Actif en recrutement
But étude	Researchers are looking for a way to treat classical Hodgkin lymphoma (cHL) that is relapsed (the cancer has come back after treatment) or refractory (current treatment has stopped working to slow or stop cancer growth). Researchers want to learn if people who receive coformulated favezelimab/pembrolizumab (MK-4280A) live longer without the cancer getting worse compared to those who receive chemotherapy
Critères d'éligibilité	• Has histologically confirmed diagnosis of classical Hodgkin lymphoma (cHL) that is 2-fluorodeoxyglucose-avid (FDG-avid). • Has relapsed (defined as disease progression after most recent therapy) or refractory (defined as failed to achieve CR or PR to most recent therapy) cHL and exhausted all available treatment options with known clinical benefit. • Has progressed on treatment with an anti-PD-(L)1 monoclonal antibody (mAb) administered either as monotherapy or in combination with other checkpoint inhibitors or other therapies. • Submits an archival (≤5 years) or newly obtained tumor tissue sample which has not been previously irradiated.
Critères d'exclusion	• Diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy. • History of central nervous system (CNS) metastases or active CNS involvement. • Has an active autoimmune disease that has required systemic treatment in past 2 years except replacement therapy. • History of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. • Has an active infection requiring systemic treatment. • History of hemophagocytic lymphohisticytosis.

- Has an active seizure disorder that is not well controlled.
- Has clinically significant (ie, active) cardiovascular disease.
- Received prior systemic anticancer therapy including investigational agents within 4 weeks before randomization.
- Received prior radiotherapy within 2 weeks of start of study intervention or radiation related toxicities requiring corticosteroids.
- Has not adequately recovered from major surgical procedure.
- Known additional malignancy that is progressing or has required active treatment within the past 3 years.
- History of human immunodeficiency virus (HIV).
- Has had an allogeneic hematopoietic stem cell or solid organ transplantation within the last 5 years.