Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase 2, Open-label Study to Evaluate the Safety and Efficacy of MK-7684A (MK-7684 [Vibostolimab] With MK-3475 [Pembrolizumab] Coformulation) in Participants With Relapsed or Refractory Hematological Malignancies
Protocole ID	MK-7684A-004 (KEYVIBE-004)
ClinicalTrials.gov ID	NCT05005442
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Coformulation de pembrolizumab/vibostolimab
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dre Kelly Davison
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Statut	Actif en recrutement
But étude	The purpose of the study is to determine the safety and tolerability of pembrolizumab/vibostolimab (MK-7684A) in hematological malignancies. This study will also evaluate the overall response rate (ORR), the duration of response (DOR), and disease control rate (DCR) following administration of pembrolizumab/vibostolimab. In addition, this study will characterize pharmacokinetic (PK) profile of vibostolimab (MK-7684).
Critères d'éligibilité	• Have confirmed relapsed/refractory classic Hodgkins Lyphoma (cHL), Primary mediastinal B-cell lymphoma (PMBCL), Follicular Lymphoma (FL), Diffuse large B-cell lymphoma (DLBCL) or Non-Hodgkins Lymphoma (NHL), or multiple myeloma (MM). **For PMBCL, DLBCL, FL, and MM:** • Must be relapsed or refractory to CAR-T-cell therapy or unable to receive it. **For DLBCL and NHL:** • Must have exhausted or be ineligible for or intolerant to all treatments, which in the opinion of the investigator are standard of care for their disease. **For NHL:** • Participants with Mantle cell lymphoma (MCL) must have received prior Bruton's tyrosine kinase inhibitor therapy. **All participants:** • Have measurable disease. • Have adequate organ function. • Participants who are Hepatitis B surface antigen (HBsAg) positive are eligible if they have received Hepatitis B (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load before allocation.

	• Must be able to provide newly obtained bone marrow biopsy or aspirate material for disease assessment. • Female participants are eligible to participate if not pregnant or breastfeeding, and at least one of the following conditions applies: Is not a woman of non child-bearing potential (WONCBP) OR Is a woman of childbearing potential (WOCBP) and using a contraceptive method that is highly effective, or be abstinent from heterosexual intercourse as their preferred and usual lifestyle.
Critères d'exclusion	**For DLBCL and NHL:** • Has lymphoplasmacytic lymphomas, Waldenstrom's macroglobulinemia, chronic lymphocytic leukemia (not associated with small lymphocytic lymphoma), Burkitt (-like) lymphoma, mature T cell and NK cell neoplasms, immunodeficiency associated lymphoproliferative neoplasms, or histiocytic and dendritic cell neoplasms. **For MM:** • Has oligo-secretory myeloma, plasma cell leukemia, smoldering multiple myeloma, or monoclonal gammopathy of undetermined significance. • Has a history of primary amyloidosis, hyperviscosity or POEMS syndrome (plasma cell dyscrasia with polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes). • Has known prior or current central nervous system (CNS) involvement. **For Epstein Barr virus (EBV) positive DLBCL:** • Associated with a solid organ transplant. **For all participants:** • A WOCBP who has a positive urine pregnancy test within 72 hours before study intervention allocation. • Has clinically significant cardiovascular disease within 12 months from first dose of study intervention. • Has a history of a second malignancy. • Any PMBCL participants that require the use of urgent cytoreductive therapy. • If the participant had major surgery, the participant must have recovered adequately from the procedure and/or any complications from the surgery before starting study intervention. • Has received prior radiotherapy within 2 weeks of start of study intervention. • Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks before the first dose of study intervention. • Has a known severe hypersensitivity to MK-7684A, vibostolimab or pembrolizumab and/or any of its excipients. • Has a known history of Human Immunodeficiency Virus (HIV) infection. • Has an active autoimmune disease that has required systemic treatment in past 2 years. • Has an active infection requiring systemic therapy. • Has a known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study. • Has present or progressive accumulation of pleural, ascitic, or pericardial fluid requiring drainage or diuretic drugs within 2 weeks before enrollment. • Has dual active HBV infection (HBsAg (+) and /or detectable HBV DNA) and Hepatitis C (HCV) infection (anti-HCV Ab (+) and detectable HCV RNA) at study entry.. • Has had an allogenic hematopoietic stem cell/solid organ transplantation within the last 5 years.