Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	A Phase 2, Multicenter, Multi Arm, Study to Evaluate Pembrolizumab (MK-3475) or MK-1308A (Co-formulated Quavonlimab (MK-1308)/Pembrolizumab) in Participants With Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Stage IV Colorectal Cancer:
Protocole ID	MK-1308A-008
ClinicalTrials.gov ID	NCT04895722
Type(s) de cancer	Côlon et rectum
Phase	Phase II
Type étude	Clinique
Médicament	Pembrolizumab ou MK-1308A
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Jamil Asselah
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Statut	Actif en recrutement
But étude	The purpose of this study is to assess the efficacy and safety of pembrolizumab or co-formulated pembrolizumab/quavonlimab in participants with MSI-H or dMMR Metastatic Stage IV Colorectal Cancer.

Critères d'éligibilité	• Has a histologically confirmed diagnosis of Stage IV CRC adenocarcinoma (as defined by American Joint Committee on Cancer [AJCC] version 8)
	• Has locally confirmed dMMR/MSI-H
	• Has a life expectancy of at least 3 months
	• Has Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1 at screening and within 3 days before Cycle 1 Day 1
	• Female participants are eligible to participate if not pregnant or breastfeeding, and not a woman of childbearing potential (WOCBP), or if a WOCBP then is using a contraceptive method that is highly effective or is abstinent on a long-term and persistent basis, during the intervention period and for at least 120 days after the last dose of study intervention
	• Has measurable disease per RECIST 1.1 as assessed by BICR
	• Has adequate organ function
	
	Cohort A:
	
	• Has been previously treated for their disease and radiographically progressed per RECIST 1.1 on or after or could not tolerate standard treatment, which must include all of the following agents if approved and locally available in the country where the participant is randomized:
	  • Fluoropyrimidine, irinotecan and oxaliplatin (capecitabine is acceptable as equivalent to fluorouracil in prior therapy)
	  • With or without an anti-vascular endothelial growth factor (VEGF) monoclonal antibody (e.g., bevacizumab)
	  • At least one of the anti-epidermal growth factor receptor (EGFR) monoclonal antibodies (cetuximab or panitumumab) for rat sarcoma viral oncogene homolog (RAS) wild-type participants with left-sided tumors
	• Must not have had prior exposure to PD-1 or PD-L1 therapies as treatment for this disease
	
	Cohort B: - Has untreated Stage IV dMMR/MSI-H CRC with no prior chemotherapy or immunotherapy for this diseaseCohort C:

	• Has radiographically progressed on-treatment with an anti-PD-1 monoclonal antibody (mAb) administered either as monotherapy or in combination with other therapies • Has had 0 to 1 prior systemic fluoropyrimidine based chemotherapy regimens • Must not have been treated in Cohort A
Critères d'exclusion	• Has received prior therapy with an agent directed to another stimulatory or coinhibitory T-cell receptor • Has received prior systemic anticancer therapy including investigational agents within 4 weeks before the first dose of study intervention • Has not recovered adequately from a surgery procedure, and/or has any complications from a prior 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 diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of study medication • Has a known additional malignancy that is progressing or has required active treatment within the past 2 years • Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis • Has severe hypersensitivity (≥Grade 3) to pembrolizumab, quavonlimab and/or any of their excipients • Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs) • Has a history of (noninfectious) pneumonitis that required steroids or has current pneumonitis • Has an active infection requiring systemic therapy (e.g., tuberculosis, known viral or bacterial infections, etc.) • Has a known history of Human Immunodeficiency Virus (HIV) infection • Has known active Hepatitis B (defined as Hepatitis B surface antigen [HBsAg] positive and/or detectable Hepatitis B Virus [HBV] deoxyribonucleic acid [DNA]) or active Hepatitis C virus (defined as HCV ribonucleic acid [RNA] [qualitative] is detected or anti-HCV antibodypositive) infection • Is pregnant, or breastfeeding, or expecting to conceive children within the projected duration of the study, starting with the Screening Visit through 120 days after the last dose of study intervention • Has had an allogenic tissue/solid organ transplant