Essai Clinique

Généré le 10 mai 2025 à partir de

Titre	A Multicenter, Randomized, Double-Blind, Phase 2, Basket Study of MK-4280A, a Coformulation of Favezelimab With Pembrolizumab in Selected Solid Tumors
Protocole ID	KeyForm-010 (MK-4280A-010)
ClinicalTrials.gov ID	NCT06036836
Type(s) de cancer	Tumeurs solides
Phase	Phase II
Type étude	Clinique
Médicament	MK-4280A, une coformulation de Favezelimab avec Pembrolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Vincent Castonguay
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Statut	Fermé
Date d'activation	04-12-2023
But étude	The purpose of this study is to evaluate pathological complete response (pCR) rate of coformulated favezelimab/pembrolizumab (MK-4280A) or pembrolizumab as assessed by blinded central pathology review (BICR) in participants with cutaneous squamous cell carcinoma (cSCC) [Cohort A] and to evaluate lenvatinib in combination with coformulated favezelimab/pembrolizumab or pembrolizumab with respect to objective response rate (ORR) per Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 as assessed by investigator in participants proficient in mismatch repair (pMMR) endometrial cancer (EC) [Cohort B].
Critères d'éligibilité	**Cohort A only** • Histologically confirmed diagnosis of resectable cutaneous squamous cell carcinoma (cSCC) as the primary site of malignancy (metastatic skin involvement from another primary cancer or from an unknown primary cancer is not permitted) • Stage II to Stage IV disease without distant metastasis (M1). cSCC tumors arising in the head and neck will be staged according to American Joint Committee on Cancer (AJCC) Edition (Ed.) 8 and cSCC tumors arising in non-head and neck locations will be staged according to Union for International Cancer Control (UICC) Ed. 8 • Is systemic treatment naïve • Archival tumor tissue sample, or newly obtained surgical resection, or biopsy sample of a tumor lesion not previously irradiated has been provided • Is an individual of any sex/gender, at least 18 years of age at the time of providing the informed consent **Cohort B only** • Histologically confirmed diagnosis of endometrial cancer (EC) that is not deficient in mismatch repair (dMMR) proficient in mismatch repair (pMMR) as documented by a local test report • Documented evidence of stage IVB (per 2009 International Federation of Gynecology and Obstetrics (FIGO) staging), recurrent, or metastatic EC, and are not candidates for curative surgery or radiation

	• Has radiographic evidence of disease progression after 1 prior systemic, platinum-based chemotherapy regimen for EC in any setting • Measurable disease per Response Evaluation Criteria In Solid Tumors (RECIST 1.1) by investigator (before first dose of study intervention) • Is assigned female sex at birth, at least 18 years of age at the time of providing the informed consent • Has adequately controlled blood pressure without antihypertensive medication **All Cohorts** • Agrees to follow contraception guidelines if a participant of childbearing potential • Has a life expectancy >3 years per investigator assessment • Has adequate organ function • Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • If positive for hepatitis B, has received antiviral therapy for ≥4 weeks and undetectable viral load prior to randomization • If positive for hepatitis C, has undetectable viral load at screening • If positive for human immunodeficiency virus (HIV), has well-controlled HIV on a stable highly active antiretroviral therapy
Critères d'exclusion	**All Cohorts** • Has known hypersensitivity to active substances or their excipients including previous clinically significant hypersensitivity reaction to treatment with other monoclonal antibody (mAb) • History of allogeneic tissue/solid organ transplant **Cohort A only** • Received prior radiotherapy to the index lesion (in-field lesion) • Participants for whom the primary site of cSCC was anogenital area (penis, scrotum, vulva, perianal region) are not eligible **Cohort B** • Has had major surgery within 3 weeks prior to first dose of study interventions • Has preexisting ≥Grade 3 gastrointestinal or non-gastrointestinal fistula • Has urine protein ≥1 g/24 hours • Has a left ventricle ejection fraction (LVEF) below the institutional (or local laboratory) normal range, as determined by multi-gated acquisition (MUGA) or echocardiogram (ECHO) • Has radiographic evidence of encasement or invasion of a major blood vessel, or of intratumoral cavitation • Has clinically significant cardiovascular disease within 12 months from first dose of study intervention