Essai Clinique

Généré le 12 mai 2025 à partir de

Titre	A Phase 3 Randomized, Open-label, Active-comparator Controlled Clinical Study of Pembrolizumab Versus Platinum Doublet Chemotherapy in Participants With Mismatch Repair Deficient (dMMR) Advanced or Recurrent Endometrial Carcinoma in the First-line Setting
Protocole ID	KEYNOTE-C93 (GOG-3064/ENGOT-en15)
ClinicalTrials.gov ID	NCT05173987
Type(s) de cancer	Endomètre
Phase	Phase III
Type étude	Clinique
Médicament	Pembrolizumab versus doublet de chimiothérapie à base de sels de platine
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Statut	Fermé
Date d'activation	20-07-2022
But étude	The purpose of this study is to assess the safety and efficacy of treatment with pembrolizumab (MK-3475) compared to a combination of carboplatin and paclitaxel in women with mismatch repair deficient (dMMR) advanced or recurrent endometrial carcinoma who have not previously been treated with prior systemic chemotherapy. The primary study hypotheses are that pembrolizumab is superior to the combination of carboplatin and paclitaxel with respect to Progression Free Survival (PFS) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) as assessed by Blinded Independent Central Review (BICR) and Overall Survival (OS).
Critères d'éligibilité	The main inclusion and exclusion criteria include but are not limited to the following: Inclusion Criteria: • Has a histologically confirmed diagnosis of Stage III or IV or recurrent Endometrial Carcinoma (EC) or carcinosarcoma (mixed Mullerian tumor) that is centrally confirmed as dMMR • Has received no prior systemic therapy for advanced EC except for the following: 1. May have received prior radiation with or without radiosensitizing chemotherapy if >2 weeks before the start of study intervention. Participants must have recovered from all radiation-related toxicities, not require corticosteroids, and not have had radiation pneumonitis. A 1-week washout is permitted for palliative radiation (≤2 weeks of radiotherapy) to non-central nervous system (CNS) disease. 2. May have received prior hormonal therapy for treatment of EC, provided that it was discontinued ≥1 week prior to randomization • Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days before randomization. • Is not pregnant or breastfeeding and agrees to not donate eggs and use a highly effective contraceptive method for 120 days after the last dose of pembrolizumab or 180 days after the last dose of chemotherapy if a woman of childbearing potential (WOCBP) • Has a negative highly sensitive pregnancy test (urine or serum) within 24 hours for urine or 72 hours for serum before the first dose of study intervention if a WOCBP

	• Provides an archival tumor tissue sample or newly obtained (core, incisional, or excisional) biopsy of a tumor lesion not previously irradiated for verification of dMMR status and histology. • Is Hepatitis B surface antigen (HBsAg) positive but has received Hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and has undetectable HBV viral load prior to randomization. • Has a history of Hepatitis C virus (HCV) infection but has undetectable HCV viral load at screening
Critères d'exclusion	• Has uterine mesenchymal tumor such as an endometrial stromal sarcoma, leiomyosarcoma, or other types of pure sarcomas. Adenosarcomas and neuroendocrine tumors are not allowed • Has EC of any histology that is proficient mismatch repair (pMMR) • Is a candidate for curative-intent surgery or curative-intent radiotherapy • Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor (e.g. cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], Tumor necrosis factor receptor superfamily, member 4 [OX 40], tumor necrosis factor receptor superfamily member 9 [CD137]) • Has received prior systemic anticancer therapy including investigational agents for EC. This includes any chemotherapy given for EC other than as a radiosensitizer • Has had a major operation and has not recovered adequately from the procedure and/or any complications from the operation before starting study intervention • Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines are allowed • Is currently participating in or has participated in a study of an investigational agent for EC, has participated in a study of an investigational agent for non-EC within 4 weeks before the first dose of study intervention, 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 or any other form of immunosuppressive therapy within 7 days prior to the first dose of study intervention • Has a known additional malignancy that is progressing or has required active treatment within the past 3 years with the exception of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (excluding carcinoma in situ of the bladder) that have undergone potentially curative therapy are not excluded • Has known active CNS metastases and/or carcinomatous meningitis • Has a known intolerance to any study intervention and/or any of its excipients • Has an active autoimmune disease that has required systemic treatment in past 2 years • Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease • Has an active infection, requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection • Has had an allogenic tissue/solid organ transplant