# Essai Clinique

Généré le 09 mai 2025 à partir de

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| Titre | Étude de phase II, ouverte et multicentrique, évaluant le lenvatinib combiné au pembrolizumab chez des sujets déjà traités pour des tumeurs solides sélectionnées |
| Protocole ID | MK-7902-005 (LEAP-005) |
| ClinicalTrials.gov ID | NCT03797326 |
| Type(s) de cancer | Tumeurs solides |
| Phase | Phase II |
| Stade | Maladie avancée ou métastatique |
| Type étude | Clinique |
| Médicament | Lenvatinib et Pembrolizumab |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>L'HOTEL-DIEU DE QUEBEC ET CRCEO<br>11 Côte du Palais, Québec, QC, G1R 2J6 |
| Ville | Québec |
| Investigateur principal | Dr Maxime Chénard-Poirier |
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| Statut | Fermé |
| But étude | The purpose of this study is to determine the safety and efficacy of combination therapy with pembrolizumab (MK-3475) and lenvatinib (E7080/MK-7902) in participants with triple negative breast cancer (TNBC), ovarian cancer, gastric cancer, colorectal cancer (CRC), glioblastoma (GBM), or biliary tract cancers (BTC). Participants will be enrolled into initial tumor-specific cohorts which will be expanded if adequate efficacy is determined. |
| Critères d'éligibilité | • Has a histologically or cytologically-documented, advanced (metastatic and/or unresectable) solid tumor that is incurable and for which prior standard systemic therapy has failed in one of the following cohorts: TNBC, Ovarian Cancer, Gastric Cancer, Colorectal Cancer: non-microsatellite instability-High/proficient mismatch repair (MSI-H/pMMR) tumor, GBM, BTC: intrahepatic, extrahepatic cholangiocarcinoma and gall bladder cancer; excludes Ampulla of Vater<br>• Must have progressed on or since the last treatment<br>• Has measurable disease per RECIST 1.1 (RANO for the GBM cohort) as assessed by the local site investigator/radiology and confirmed by BICR<br>• Has provided archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion not previously irradiated<br>• Male participants agree to use approved contraception during the treatment period and for at least 120 days after the last dose of study treatment, and refrain from donating sperm during this period<br>• Female participants are not pregnant or breastfeeding, and are not a woman of childbearing potential (WOCBP), OR are a WOCBP that agrees to use contraception during the treatment period (or 14 days prior to the initiation of study treatment for oral contraception) and for at least 120 days after the last dose of study treatment<br>• Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 7 days of study treatment initiation<br>• Has adequate organ function<br>For Triple Negative Breast Cancer Participants:<br>• Has received one or 2 prior lines of therapy |

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| | • Has Lactate Dehydrogenase (LDH) <2.0 x Upper Limit of Normal (ULN)<br><br>For Ovarian Cancer Participants:<br><br>• Has received 3 prior lines of therapy<br><br>For Gastric Cancer Participants:<br><br>• Has received 2 prior lines of therapy<br><br>For Colorectal Cancer Participants:<br><br>• Has received 2 prior lines of therapy<br>• Has a locally determined non-MSI-H/pMMR tumor<br><br>For GBM Participants:<br><br>• Has failed initial systemic therapy for newly diagnosed GBM<br>• Have the following time periods elapsed before the projected start of scheduled study treatment: 1) at least 3 weeks from prior surgical resection, 2) at least 1 week from stereotactic biopsy, 3) at least 6 months from completion of prior radiotherapy, 4) at least 4 weeks (or 5 half-lives, whichever is shorter) from any investigational agent, 5) at least 4 weeks from cytotoxic therapy, 6) at least 6 weeks from antibodies, 7) at least 4 weeks (or 5 half-lives, whichever is shorter) from other antitumor therapies and 1 week for cancer vaccines<br>• Be neurologically stable (e.g. without a progression of neurologic symptoms or requiring escalating doses of systemic steroid therapy within last 2 weeks) and clinically stable<br>• Has histologically confirmed World Health Organization (WHO) Grade IV GBM<br><br>For Biliary Tract Cancer Participants:<br><br>• Has received 1 prior line of therapy<br>• Child-Pugh Score, Class A: well-compensated disease. Child-Pugh Score of 5-6 |
| Critères d'exclusion | • Has presence of gastrointestinal condition including malabsorption that might affect the absorption of lenvatinib<br>• Radiographic evidence of major blood vessel invasion/infiltration<br>• Clinical significant hemoptysis or tumor bleeding within 2 weeks prior to the first dose of study treatment<br>• Has significant cardiovascular impairment within 12 months of the first dose of study treatment: such as history of congestive heart failure greater than New York Heart Association (NYHA) Class II, unstable angina, myocardial infarction or cerebrovascular accident (CVA), or cardiac arrhythmia associated with hemodynamic instability<br>• Has a history of arterial thromboembolism within 12 months of start of study treatment<br>• Has a known additional malignancy that is progressing or has required active treatment within the past 3 years.<br>• Serious nonhealing wound, ulcer or bone fracture<br>• Biologic response modifiers (e.g. granulocyte colony-stimulating factor) within 4 weeks before study entry.<br>• Has received prior therapy with lenvatinib, an anti-PD-1, anti-PD-L1, or anti PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory 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])<br>• Has received prior systemic anti-cancer therapy including investigational agents within 4 weeks or 5 times the half-life time, whichever is shorter prior to study treatment start<br>• If participant received major surgery, they must have recovered adequately from the toxicity and/or complications from the intervention prior to starting study treatment<br>• Has received prior radiotherapy within 2 weeks of start of study treatment. 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<br>• Has received a live vaccine within 30 days prior to the first dose of study treatment<br>• Known intolerance to study treatment (or any of the excipients)<br>• Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment<br>• 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 the first dose of study treatment<br>• Has known active CNS metastases and/or carcinomatous meningitis<br>• Has tumors involving the brain stem<br>• Has severe hypersensitivity (≥Grade 3) to pembrolizumab and/or any of its excipients<br>• Has an active autoimmune disease that has required systemic treatment in past 2 years<br>• Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis<br>• Has an active infection requiring systemic therapy<br>• Has a known history of human immunodeficiency virus (HIV) infection<br>• Has a known history of hepatitis B or known active hepatitis C virus infection<br>• Has a known history of active tuberculosis (TB; Bacillus tuberculosis)<br>• Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study treatment |

- Has had an allogenic tissue/solid organ transplant (large organ transplants, stem-cell transplant requiring chronic immunosuppressant therapy necessary to prevent graft rejection)

For Colorectal Cancer Participants:

- Has MSI-H/dMMR disease

For GBM Participants:

- Has carcinomatous meningitis
- Has recurrent tumor greater than 6 cm in maximum diameter
- Has tumor primarily localized to the brainstem or spinal cord
- Has presence of multifocal tumor, diffuse leptomeningeal or extracranial disease
- Has evidence of intratumoral or peritumoral hemorrhage on baseline magnetic resonance imaging (MRI) scan other than those that are grade ≤ 1 and either post-operative or stable on at least 2 consecutive MRI scans