# Essai Clinique

Généré le 07 mai 2024 à partir de

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| Titre | Essai comparant l'association pembrolizumab plus enzalutamide et l'association placebo plus enzalutamide chez des patients atteints d'un cancer de la prostate métastatique résistant à la castration |
| Protocole ID | MK-3475-641 |
| ClinicalTrials.gov ID | NCT03834493 |
| Type(s) de cancer | Prostate |
| Phase | Phase III |
| Stade | Résistant à la castration - métastatique |
| Type étude | Traitement |
| Médicament | Pembrolizumab + enzalutamide |
| Institution | CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE<br>HOPITAL FLEURIMONT<br>3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4 |
| Ville | Sherbrooke |
| Investigateur principal | Dr Michel Pavic |
| Coordonnateur | Anick Champoux<br>819-346-1110 poste 12811 |
| Statut | Fermé |
| But étude | The purpose of this study is to assess the efficacy and safety of the combination of pembrolizumab (MK-3475) and enzalutamide in the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) who have not received chemotherapy for mCRPC, are abiraterone-naïve, or are intolerant to or progressed on abiraterone acetate. There are two primary study hypotheses: Hypothesis 1: The combination of pembrolizumab plus enzalutamide is superior to placebo plus enzalutamide with respect to Overall Survival (OS). Hypothesis 2: The combination of pembrolizumab plus enzalutamide is superior to placebo plus enzalutamide with respect to Radiographic Progression-free Survival (rPFS) per Prostate Cancer Working Group (PCWG)-modified Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) as assessed by blinded independent central review. |
| Critères d'éligibilité | • Has histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology<br>• Has prostate cancer progression while on androgen deprivation therapy (or post bilateral orchiectomy) within 6 months prior to screening<br>• Has current evidence of metastatic disease documented by either bone lesions on bone scan and/or soft tissue disease by computed tomography/magnetic resonance imaging (CT/MRI)<br>• Is abiraterone-naive or are intolerant to/progressed on abiraterone<br>• Has ongoing androgen deprivation with serum testosterone <50 ng/mL (<2.0 nM)<br>• Participants receiving bone resorptive therapy (including, but not limited to, bisphosphonate or denosumab) must have been on stable doses prior to randomization<br>• Participants must agree to the following during the study treatment period and for ≥120 days after the last dose of study treatment: Refrain from donating sperm PLUS Use contraception unless confirmed to be azoospermic (vasectomized or secondary to medical cause)<br>• Participants must agree to use male condom when engaging in any activity that allows for passage of ejaculate to another person of any sex<br>• Has provided newly obtained core or excisional biopsy (obtained within 12 months of screening) from soft tissue not previously irradiated (samples from tumors progressing in a prior site of radiation are allowed). Participants with bone only or bone predominant disease may provide a |

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| | bone biopsy sample<br>• Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 assessed within 7 days of randomization. |
| Critères d'exclusion | • Has a known additional malignancy that is progressing or has required active treatment in the last 3 years<br>• Has an active autoimmune disease that has required systemic treatment in past 2 years<br>• Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy<br>• Has undergone major surgery including local prostate intervention (excluding prostate biopsy) within 28 days prior to randomization and not recovered adequately from the toxicities and/or complications<br>• Has a gastrointestinal disorder affecting absorption or is unable to swallow tablets/capsules<br>• Has an active infection (including tuberculosis) requiring systemic therapy<br>• Has a history of (non-infectious) pneumonitis that required steroids or current pneumonitis<br>• Has known active human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) infection<br>• Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis<br>• Has severe hypersensitivity (≥Grade 3) to pembrolizumab and/or any of its excipients<br>• Has a history of seizure or any condition that may predispose to seizure<br>• Has a history of loss of consciousness within 12 months of screening<br>• Has hypotension (systolic blood pressure <86 millimeters of mercury [mmHg]) or uncontrolled hypertension (systolic blood pressure >170 mmHg or diastolic blood pressure >105 mmHg) at the screening visit<br>• Has bradycardia (heart rate of <50 beats per minute) on the screening electrocardiogram (ECG)<br>• Has history of prostate cancer progression on ketoconazole<br>• Has had prior treatment with enzalutamide, apalutamide, or darolutamide<br>• Has received prior therapy with an anti-programmed cell death-1 (anti-PD-1), anti-programmed cell death-ligand 1 (anti-PD-L1), or anti PD-L2 agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor<br>• Has received prior treatment with radium or other therapeutic radiopharmaceuticals for prostate cancer<br>• Has received prior treatment with docetaxel or another chemotherapy agent for mCRPC<br>• Has had a prior anti-cancer monoclonal antibody (mAb) prior to randomization<br>• Has used herbal products that may have hormonal anti-prostate cancer activity and/or are known to decrease PSA levels (eg, saw palmetto) prior to randomization<br>• Has received a live vaccine within 30 days prior to randomization<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 "superscan" bone scan<br>• Is 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<br>• Has had an allogenic tissue/solid organ transplant |