



Essai Clinique

Généré le 09 mai 2025 à partir de

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| Titre | Étude de phase III à répartition aléatoire portant sur la cystectomie en association avec le pembrolizumab périopératoire par rapport à la cystectomie en monothérapie chez des participants non admissibles au cisplatine atteints d'un cancer de la vessie avec envahissement musculaire |
| Protocole ID | MK-3475-905 (KEYNOTE-905) |
| ClinicalTrials.gov ID | NCT03924895 |
| Type(s) de cancer | Vessie/urothélial |
| Phase | Phase III |
| Type étude | Traitement |
| Médicament | Pembrolizumab |
| Institution | CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2 |
| Ville | |
| Investigateur principal | Dr Maurice Anidjar |
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| Statut | Fermé |
| But étude | A global, randomized phase III study to evaluate perioperative pembrolizumab with radical cystectomy + pelvic lymph node dissection (RC+PLND) versus RC+PLND alone in cisplatin-ineligible patients with muscle-invasive bladder cancer (MIBC). |
| Critères d'éligibilité | <ul style="list-style-type: none">• Histologically confirmed diagnosis of muscle invasive bladder cancer (T2-T4aN0M0) with predominant (≥50%) urothelial histology. Participants with mixed histology are eligible provided the urothelial component is ≥50%. Urothelial carcinomas not originating from the bladder are not eligible. Participants whose tumors contain any neuroendocrine component are not eligible.• Clinically non-metastatic bladder cancer determined by imaging• Eligible for radical cystectomy (RC) + pelvic lymph node dissection (PLND), and agreement to undergo curative intent standard RC + PLND (including prostatectomy if applicable)• Ineligible for treatment with cisplatin, as defined by meeting at least one of the following criteria:<ul style="list-style-type: none">• Impaired renal function with measured or calculated CrCl 30 to 59 mL/min• Eastern Cooperative Oncology Group (ECOG) Performance Status 2• Common Terminology Criteria for Adverse Events (CTCAE) v.4 Grade ≥2 audiometric hearing loss• CTCAE v.4 Grade ≥2 peripheral neuropathy• New York Heart Association (NYHA) Class III heart failure• Transurethral resection (TUR) of a bladder tumor that is submitted and adequate for evaluation of histology, muscle invasion and PD-L1 status• ECOG performance status of 0, 1, or 2• Adequate organ function |
| Critères d'exclusion | <ul style="list-style-type: none">• Known additional non-urothelial malignancy that is progressing or has required active treatment ≤3 years of study randomization, with certain exceptions• Received any prior systemic anti-neoplastic treatment for muscle-invasive bladder cancer (MIBC)• Received prior therapy with a anti-programmed cell death protein 1 (PD-1), anti-programmed death-ligand 1 (PD-L1), or anti-programmed cell death 1 ligand 2 (PD-L2), or with an agent directed to another stimulatory or co-inhibitory T-cell receptor• Received prior systemic anti-cancer therapy including investigational agents within 3 years prior |

to randomization

- Received any prior radiotherapy to the bladder
- Received a live vaccine within 30 days prior to the first dose of study drug
- Current participation in or participation in a study of an investigational agent or use of an investigational device within 4 weeks prior to the first dose of study intervention
- Diagnosis of immunodeficiency or receipt of chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study drug
- Hypersensitivity to monoclonal antibodies (including pembrolizumab) and/or any of their excipients
- Active autoimmune disease that has required systemic therapy in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic therapy and is allowed.
- History of (non-infectious) pneumonitis that required steroids, or current pneumonitis.
- Active infection requiring systemic therapy