Essai Clinique

Généré le 04 mai 2024 à partir de

Titre	A Phase III, Randomized, Double-blind Study to Evaluate Pembrolizumab Plus Chemotherapy vs Placebo Plus Chemotherapy as Neoadjuvant Therapy and Pembrolizumab vs Placebo as Adjuvant Therapy for Triple Negative Breast Cancer (TNBC)
Protocole ID	MK-3475-522/KEYNOTE-522
ClinicalTrials.gov ID	NCT03036488
Type(s) de cancer	Sein
Phase	Phase III
Stade	Adjuvant
Type étude	Traitement
Médicament	Pembrolizumab + chimiothérapie
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
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Statut	Fermé
But étude	The purpose of this study is to evaluate the efficacy and safety of pembrolizumab (MK-3475) plus chemotherapy vs placebo plus chemotherapy as neoadjuvant therapy and pembrolizumab vs placebo as adjuvant therapy in participants who have triple negative breast cancer (TNBC).
Critères d'éligibilité	• Has newly diagnosed, locally advanced, centrally confirmed TNBC, as defined by the most recent American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines. • Has previously untreated locally advanced non-metastatic (M0) TNBC • Provides a core needle biopsy consisting of at least 2 separate tumor cores from the primary tumor at screening to the central laboratory. • Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 performed within 10 days of treatment initiation. • Demonstrates adequate organ function. • Males and female participants of childbearing potential must be willing to use an adequate method of contraception for the course of the study through 12 months after the last dose of study treatment for participants who have received cyclophosphamide, and 6 months after the last dose of study treatment for participants who did not.
Critères d'exclusion	• Has a history of invasive malignancy ≤5 years prior to signing informed consent except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer. • Has received prior chemotherapy, targeted therapy, and radiation therapy within the past 12 months. • Has received prior therapy with an anti-programmed cell death protein 1 (anti-PD-1), anti-programmed death - ligand 1 (anti-PD-L1), or anti-PD-L2 agent or with an agent directed to another co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated antigen-4 [CTLA-4], OX-40, CD137 [tumor necrosis factor receptor superfamily member 9 (TNFRSF9)]) or has previously participated in a pembrolizumab (MK-3475) clinical study.

- Is currently participating in or has participated in an interventional clinical study with an investigational compound or device within 4 weeks of the first dose of treatment in this current study.
- Has received a live vaccine within 30 days of the first dose of study treatment.
- Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs).
- Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study treatment.
- Has a known history of Human Immunodeficiency Virus (HIV).
- Has known active Hepatitis B or Hepatitis C.
- Has a history of (non-infectious) pneumonitis that required steroids or current pneumonitis.
- Has an active infection requiring systemic therapy.
- Has significant cardiovascular disease, such as: history of myocardial infarction, acute coronary syndrome or coronary angioplasty/stenting/bypass grafting within the last 6 months OR congestive heart failure (CHF) New York Heart Association (NYHA) Class II-IV or history of CHF NYHA Class III or IV.
- Is pregnant or breastfeeding, or expecting to conceive children within the projected duration of the study, starting with the screening visit through 12 months after the last dose of study treatment for participants who have received cyclophosphamide, and for 6 months after the last dose of study treatment for participants who have not.
- Has a known hypersensitivity to the components of the study treatment or its analogs.
- Has a known history of active tuberculosis (TB, Bacillus Tuberculosis).