Essai Clinique

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Titre	Étude de phase III randomisée pour évaluer l'efficacité et la sécurité de l'Atezolizumab (anticorps anti-PD-L1) combiné à une chimiothérapie néo-adjuvante basée sur une combinaison anthracycline/nab-Paclitaxel comparée à une combinaison placebo et chimiothérapie chez des patients avec un cancer du sein primaire invasif triple-négatif.
Protocole ID	WO39392 (IMpassion031)
ClinicalTrials.gov ID	NCT03197935
Type(s) de cancer	Sein
Phase	Phase III
Stade	Néo-adjuvant/induction
Type étude	Traitement
Médicament	Atezolizumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
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Statut	Fermé
But étude	This is a global Phase III, double-blind, randomized, placebo-controlled study designed to evaluate the efficacy and safety of neoadjuvant treatment with atezolizumab (anti-programmed death-ligand 1 [anti-PD-L1] antibody) and nab-paclitaxel followed by doxorubicin and cyclophosphamide (nab-pac-AC), or placebo and nab-pac−AC in participants eligible for surgery with initial clinically assessed triple-negative breast cancer (TNBC).
Critères d'éligibilité	• Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 • Histologically documented TNBC (negative human epidermal growth factor receptor 2 [HER2], estrogen receptor [ER], and progesterone receptor [PgR] status) • Confirmed tumor programmed death−ligand 1 (PD-L1) evaluation as documented through central testing of a representative tumor tissue specimen • Primary breast tumor size of greater than (>) 2 centimeters (cm) by at least one radiographic or clinical measurement • Stage at presentation: cT2-cT4, cN0-cN3, cM0 • Participant agreement to undergo appropriate surgical management including axillary lymph node surgery and partial or total mastectomy after completion of neoadjuvant treatment • Baseline left ventricular ejection fraction (LVEF) greater than or equal to (>=) 53 percent (%) measured by echocardiogram (ECHO) or multiple-gated acquisition (MUGA) scans • Adequate hematologic and end-organ function • Representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen in paraffin blocks (preferred) or at least 20 unstained slides, with an associated pathology report documenting ER, PgR, and HER2 negativity

Critères d'exclusion	• Prior history of invasive breast cancer • Stage 4 (metastatic) breast cancer • Prior systemic therapy for treatment and prevention of breast cancer • Previous therapy with anthracyclines or taxanes for any malignancy • History of ductal carcinoma in situ (DCIS), except for participants treated exclusively with mastectomy >5 years prior to diagnosis of current breast cancer • History of pleomorphic lobular carcinoma in situ (LCIS), except for participants surgically managed >5 years prior to diagnosis of current breast cancer • Bilateral breast cancer • Undergone incisional and/or excisional biopsy of primary tumor and/or axillary lymph nodes • Axillary lymph node dissection prior to initiation of neoadjuvant therapy • History of other malignancy within 5 years prior to screening, with the exception of those with a negligible risk of metastasis or death • Cardiopulmonary dysfunction • History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins • Known hypersensitivity to biopharmaceuticals produced in Chinese hamster ovary cells • Known allergy or hypersensitivity to the components of the formulations of atezolizumab, nab-paclitaxel, cyclophosphamide, or doxorubicin, filgrastim or pegfilgrastim • Active or history of autoimmune disease or immune deficiency diseases except history of autoimmune-related hypothyroidism, controlled Type 1 diabetes mellitus, and dermatologic manifestations of eczema, psoriasis, lichen simplex chronicus, or vitiligo (e.g., participants with psoriatic arthritis are excluded) • History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted • Positive human immunodeficiency virus (HIV) test at screening • Active hepatitis B and hepatitis C virus infection • Active tuberculosis • Severe infections within 4 weeks prior to initiation of study treatment, including but not limited to hospitalization for complications of infection, bacteremia, or severe pneumonia • Treatment with therapeutic oral or IV antibiotics within 2 weeks prior to initiation of study treatment, except prophylactic antibiotics • Major surgical procedure within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during the course of the study • Prior allogeneic stem cell or solid organ transplantation • Administration of a live attenuated vaccine within 4 weeks prior to initiation of study treatment or anticipation of need for such a vaccine during the study • Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the participant at high risk from treatment complications • Prior treatment with cluster of differentiation 137 (CD137) agonists or immune checkpoint-blockade therapies, including anti-cluster of differentiation 40 (anti-CD40), anti-cytotoxic T-lymphocyte-associated protein 4 (anti-CTLA-4), anti-programmed death-1 (anti-PD-1), and anti-PD-L1 therapeutic antibodies • Treatment with systemic immunostimulatory agents within 4 weeks or 5 half-lives of the drug, whichever is longer, prior to initiation of study treatment • Treatment with systemic immunosuppressive medications within 2 weeks prior to initiation of study treatment or anticipation of need for systemic immunosuppressive medications during the study