Essai Clinique

Généré le 02 mai 2024 à partir de

Titre	A Randomized, Multicenter, Double-blind, Placebo-controlled Phase 3 Study of Nivolumab Versus Placebo in Combination With Neoadjuvant Chemotherapy and Adjuvant Endocrine Therapy in Patients With High-risk, Estrogen Receptor-Positive (ER+), Human Epidermal Growth Factor Receptor 2-Negative (HER2-) Primary Breast Cancer
Protocole ID	CA209-7FL
ClinicalTrials.gov ID	NCT04109066
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Traitement
Médicament	Nivolumab vs placebo + paclitaxel
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 Jean-François Boileau
Coordonnateur	Connie Pantalena 514-340-8222 poste 26832
Statut	Fermé
But étude	A randomized multi-arm study evaluating the safety and efficacy of nivolumab versus placebo in combination with paclitaxel in participants with ER+/HER2- breast cancer
Critères d'éligibilité	• Participant has untreated, unilateral invasive, histologically confirmed, localized invasive breast ductal carcinoma that includes either T1c-T2 (tumor size ≥2 cm), clinical node stage (cN)1-cN2, or T3-T4, cN0-cN2. Note: Inflammatory breast cancer is allowed. • Participant has centrally confirmed ER+ invasive breast cancer with or without progesterone receptor expression, according to the most recent American Society of Clinical Oncology/College of American Pathologist guidelines. • Participant must agree to provide tumor tissue at baseline and at surgery. • Participant must be deemed eligible for neoadjuvant chemotherapy. • Participant must be deemed eligible for surgery and must agree to undergo surgery after completion of neoadjuvant therapy. • Women and men must agree to follow instructions for methods of contraception. • Participant must have an Eastern Cooperative Oncology Group (ECOG) scale performance status of 0 or 1.
Critères d'exclusion	• Participant who is breastfeeding, pregnant, or expecting to conceive or father children within the projected duration of the study, starting with the screening through 12 months for participants who receive cyclophosphamide, or 6 months for participants who do not receive cyclophosphamide, after the last dose of study treatment. • Prior treatment with chemotherapy, endocrine therapy, targeted therapy, and/or radiation administered for the currently diagnosed breast cancer, or where upfront chemotherapy is judged clinically inappropriate as optimal neoadjuvant treatment. • Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways, or history of allergy, or hypersensitivity to study medication. • Participant has significant cardiovascular disease such as left ventricular ejection fraction (LVEF) < 50% at baseline as assessed by echocardiography (ECHO) or multigated acquisition

(MUGA) scan performed at screening, or Class III or IV myocardial disease as described by the New York Heart Association.
- Other inclusion/exclusion criteria may apply.