Essai Clinique

Généré le 28 avr. 2024 à partir de

Titre	Essai clinique de phase III à répartition aléatoire, à double insu et contrôlé par placebo visant à évaluer l'efficacité et l'innocuité de l'atézolizumab ou du placebo en association avec le schéma néoadjuvant doxorubicine + cyclophosphamide, suivi du schéma paclitaxel + trastuzumab + pertuzumab dans en présence d'un cancer du sein précoce positif pour HER2.
Protocole ID	IMpassion050
ClinicalTrials.gov ID	NCT03726879
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Traitement
Médicament	Atezolizumab avec Doxorubicine + Cyclophosphamide en néo-adjuvant suivi de Paclitaxel + Trastuzumab + Pertuzumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL H HOPITAL DU SAINT-SACREMENT 1050 Ch Ste-Foy, Québec, QC, G1S 4L8
Ville	Québec
Investigateur principal	Dre Louise Provencher
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Statut	Fermé
But étude	This study (also known as IMpassion050) will evaluate the efficacy and safety of atezolizumab compared with placebo when given in combination with neoadjuvant dose-dense anthracycline (doxorubicin) + cyclophosphamide followed by paclitaxel + trastuzumab + pertuzumab (ddAC-PacHP) in patients with early HER2-positive breast cancer (T2-4, N1-3, M0).
Critères d'éligibilité	• Confirmed diagnosis of HER2-positive breast cancer, and hormonal and PD-L1 status, as documented through central testing of a representative tumor tissue specimen • Primary breast tumor size of > 2 cm by any radiographic measurement • Stage at presentation: T2-T4, N1-N3, M0 as determined by AJCC staging system, 8th edition • Pathologic confirmation of nodal involvement with malignancy must be determined by fine needle aspiration or core-needle biopsy. Surgical excision of lymph nodes is not permitted. • Patients with multifocal tumors are eligible provided at least one focus is sampled and centrally confirmed as HER2-positive. • Patients with multicentric tumors are eligible provided all discrete lesions are sampled and centrally confirmed as HER2-positive. • Eastern Cooperative Oncology Group Performance Status of 0 or 1 • Baseline LVEF >= 55% measured by echocardiogram (ECHO) or multiple-gated acquisition (MUGA) scans • Adequate hematologic and end-organ function obtained within 14 days prior to initiation of study treatment • For women of childbearing potential: agreement to remain abstinent or use contraceptive methods, and agreement to refrain from donating eggs • For men: agreement to remain abstinent or use contraceptive measures, and agreement to refrain from donating sperm

Critères d'exclusion	• Prior history of invasive breast cancer • Stage IV (metastatic) breast cancer • Patients with synchronous bilateral invasive breast cancer • Prior systemic therapy for treatment of breast cancer • Previous therapy with anthracyclines or taxanes for any malignancy • Ulcerating or inflammatory breast cancer • Undergone incisional and/or excisional biopsy of primary tumor and/or axillary lymph nodes • Sentinel lymph node procedure or 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 patients who have a negligible risk of metastasis or death • Cardiopulmonary dysfunction • Dyspnea at rest • Active or history of autoimmune disease or immune deficiency • Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after the final dose of atezolizumab/placebo, 6 months after the final dose of doxorubicin, 12 months after the final dose of cyclophosphamide, 6 months after the final dose of paclitaxel, or 7 months after the final dose of trastuzumab, pertuzumab, or trastuzumab emtansine whichever occurs last Exclusion Criteria Related to Trastuzumab Emtansine in the Adjuvant Setting: • Patients who achieved pCR • Evidence of clinically evident gross residual or recurrent disease following neoadjuvant therapy and surgery • Unable to complete surgery with curative intent after conclusion of neoadjuvant systemic therapy • Patient discontinued treatment with trastuzumab because of toxicity during the neoadjuvant phase of the study • Clinically significant history of liver disease, including cirrhosis, current alcohol abuse, autoimmune hepatic disorders, or sclerosis cholangitis • Patients with Grade >=2 peripheral neuropathy • Prior treatment with trastuzumab emtansine