Essai Clinique

Généré le 23 mai 2025 à partir de

Titre	A Phase III, Open-label, Randomised Study of Neoadjuvant Datopotamab Deruxtecan (Dato-DXd) Plus Durvalumab Followed by Adjuvant Durvalumab With or Without Chemotherapy Versus Neoadjuvant Pembrolizumab Plus Chemotherapy Followed by Adjuvant Pembrolizumab With or Without Chemotherapy for the Treatment of Adult Patients With Previously Untreated Triple-Negative or Hormone Receptor-low/HER2-negative Breast Cancer
Protocole ID	TROPION-Breast04
ClinicalTrials.gov ID	NCT06112379
Type(s) de cancer	Sein
Phase	Phase III
Type étude	Clinique
Médicament	Datopotamab deruxtecan en néoadjuvant + durvalumab suivi de durvalumab en adjuvant avec ou sans chiniothérapie versus pembrolizumab en néoadjuvant + chimiothérapie suivi de pembrolizumab en adjuvant avec ou sans chiniothérapie
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
Investigateur principal	Dr Michel Pavic
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Statut	Actif en recrutement
Date d'activation	23-02-2024
But étude	This is a Phase III, 2-arm, randomised, open-label, multicentre, global study assessing the efficacy and safety of neoadjuvant Dato-DXd plus durvalumab followed by adjuvant durvalumab with or without chemotherapy compared with neoadjuvant pembrolizumab plus chemotherapy followed by adjuvant pembrolizumab with or without chemotherapy in participants with previously untreated TNBC or hormone receptor-low/HER2-negative breast cancer.
Critères d'éligibilité	• Participant must be ≥ 18 years, at the time of signing the ICF. • Histologically confirmed Stage II or III unilateral or bilateral primary invasive TNBC or hormone receptor-low/HER2-negative breast cancer • ECOG PS of 0 or 1 • Provision of acceptable tumor sample • Adequate bone marrow reserve and organ function • Contraceptive use by males or females should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies.
Critères d'exclusion	• History of another primary malignancy except for malignancy treated with curative intent with no known active disease within 3 years before randomization and of low potential risk for recurrence. • Evidence of distant disease. • Clinically significant corneal disease. • Has active or uncontrolled hepatitis B or C virus infection. • Known HIV infection that is not well controlled. • Uncontrolled infection requiring i.v. antibiotics, antivirals or antifungals; suspected infections; or inability to rule out infections.

- Known to have active tuberculosis infection
- Resting ECG with clinically significant abnormal findings.
- Uncontrolled or significant cardiac disease.
- History of non-infectious ILD/pneumonitis
- Any prior or concurrent surgery, radiotherapy or systemic anticancer therapy for TNBC or hormone receptor-low/HER2-negative breast cancer
- For females only: is pregnant (confirmed with positive serum pregnancy test) or breastfeeding, or planning to become pregnant.
- Female participants should refrain from breastfeeding from enrolment throughout the study and for at least 7 months after last dose of study intervention, or as dictated by local PI for SoC if longer.