Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Durvalumab and Carboplatin Versus Pembrolizumab in Combination With Platinum-based Chemotherapy for the First-line Treatment of Patients With Locally Advanced or Metastatic NSCLC Without Actionable Genomic Alterations
Protocole ID	AVANZAR
ClinicalTrials.gov ID	NCT05687266
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase III
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	Datopotamab Deruxtecan en associtaion avec le durvalumab et carboplatine versus pembrolizumab en association avec une chimiothérapie à base de platine
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Scott Owen
Coordonnateur	Nicola Raby 514-934-1934 poste 34095
Statut	Actif en recrutement
Date d'activation	03-04-2023
But étude	This is a Phase III, randomized, open-label, multicenter, global study to compare the efficacy and safety of Datopotamab Deruxtecan (Dato-DXd) in combination with durvalumab and carboplatin compared with pembrolizumab in combination with histology-specific platinum-based chemotherapy as first-line treatment of adults with stage IIIB, IIIC, or IV NSCLC without actionable genomic alterations (including sensitizing EGFR mutations, and ALK and ROS1 rearrangements).
Critères d'éligibilité	• Participants ≥ 18 years at screening • Participants with histologically or cytologically documented NSCLC that is Stage IIIB or IIIC disease not amenable for surgical resection or definitive chemoradiation or Stage IV metastatic NSCLC disease at the time of randomisation, who have not received prior chemotherapy or other systemic therapy for first-line Stage IIIB, IIIC or IV • Lacks sensitising EGFR tumour tissue mutation and ALK and ROS1 rearrangements and has no documented tumour genomic alterations in NTRK, BRAF, RET, MET or other actionable driver oncogenes with approved therapies (actionable genomic alterations). • ECOG PS of 0 or 1 • Archival tumour tissue collected prior to signing of ICF • Has adequate bone marrow reserve and organ function within 7 days before randomisation

Critères d'exclusion	• History of another primary malignancy except for malignancy treated with curative intent with no known active disease within 3 years before the first dose of study intervention and of low potential risk for recurrence • Mixed small-cell lung cancer and NSCLC histology; sarcomatoid variant of NSCLC • Persistent toxicities caused by previous anti-cancer therapy not yet improved to Grade ≤ 1 or baseline (with exceptions) • Active or prior documented autoimmune, connective tissue or inflammatory disorders (with exceptions) • Spinal cord compression or brain metastases unless asymptomatic, stable, not requiring steroids for at least 7 days prior to randomisation, and a minimum of 2 weeks have elapsed between the end of radiotherapy and study enrollment • History of leptomeningeal carcinomatosis • Clinically significant corneal disease • Known active or uncontrolled hepatitis B or C virus infection • Known HIV infection that is not well controlled • History of non-infectious ILD/pneumonitis that required steroids, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening