Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Étude multicentrique de phase II/III évaluant l'efficacité et l'innocuité de multiples traitements ciblés dans le traitement de patients atteints du cancer du poumon non à petites cellules (CPNPC) avancé ou métastatique présentant des mutations somatiques actionnables détectées dans le sang.
Protocole ID	BO29554 (B-FAST)
ClinicalTrials.gov ID	NCT03178552
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Alectinib vs Atezolizumab vs Pemetrexed vs Cisplatine vs vs Carboplatine vs Gemcitabine
Institution	INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUEBEC - UL
Ville	Québec
Investigateur principal	Dre Catherine Labbé
Coordonnateur	Brigitte Fortin 418-656-8711 poste 2639
Statut	Fermé
But étude	This is a phase 2/3, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in combination in participants with unresectable, advanced or metastatic NSCLC determined to harbor oncogenic somatic mutations or positive by tumor mutational burden (TMB) assay as identified by two blood-based next-generation sequencing (NGS) circulating tumor DNA (ctDNA) assays.
Critères d'éligibilité	• No prior systemic treatment for unresectable stage IIIB or IV NSCLC • Histologically or cytologically confirmed diagnosis of unresectable Stage IIIb not amenable to treatment with combined modality chemoradiation (advanced) or Stage IV (metastatic) NSCLC • Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2 • Measurable disease • Adequate recovery from most recent systemic or local treatment for cancer • Adequate organ function • Life expectancy greater than or equal to (>/=) 12 weeks • For female participants of childbearing potential and male participants, willingness to use acceptable methods of contraception
Critères d'exclusion	• Inability to swallow oral medication • Women who are pregnant or lactating • Symptomatic, untreated CNS metastases • History of malignancy other than NSLCL within 5 years prior to screening with the exception of malignancies with negligible risk of metastasis or death • Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or greater), myocardial infarction, or cerebrovascular accident within 3 months prior to randomization, unstable arrhythmias, or unstable angina • Known human immunodeficiency virus (HIV) positivity or autoimmune deficiency syndrome (AIDS)-related illness • Either a concurrent condition or history of a prior condition that places the patient at unacceptable risk if he/she were treated with the study drug or confounds the ability to interpret

data from the study
- Inability to comply with other requirements of the protocol