



# Essai Clinique

Généré le 04 mai 2024 à partir de

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| 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   | <a href="#">NCT03178552</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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             | CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL<br> HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS<br>3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Ville                   | Montréal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Investigateur principal | Dr Victor Cohen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Coordonnateur           | Caroline Lambert<br>514-340-8222                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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  | <ul style="list-style-type: none"><li>• No prior systemic treatment for unresectable stage IIIB or IV NSCLC</li><li>• Histologically or cytologically confirmed diagnosis of unresectable Stage IIIB not amenable to treatment with combined modality chemoradiation (advanced) or Stage IV (metastatic) NSCLC</li><li>• Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2</li><li>• Measurable disease</li><li>• Adequate recovery from most recent systemic or local treatment for cancer</li><li>• Adequate organ function</li><li>• Life expectancy greater than or equal to (<math>\geq</math>) 12 weeks</li><li>• For female participants of childbearing potential and male participants, willingness to use acceptable methods of contraception</li></ul> |
| Critères d'exclusion    | <ul style="list-style-type: none"><li>• Inability to swallow oral medication</li><li>• Women who are pregnant or lactating</li><li>• Symptomatic, untreated CNS metastases</li><li>• History of malignancy other than NSCLC within 5 years prior to screening with the exception of malignancies with negligible risk of metastasis or death</li><li>• 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</li><li>• Known human immunodeficiency virus (HIV) positivity or autoimmune deficiency syndrome (AIDS)-related illness</li></ul>                                        |

- 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