Essai Clinique

Généré le 19 mai 2024 à partir de

Titre	Brigatinib in Patients With Anaplastic Lymphoma Kinase-Positive (ALK+), Advanced Non-Small-Cell Lung Cancer (NSCLC) Progressed on Alectinib or Ceritinib
Protocole ID	Brigatinib-2002
ClinicalTrials.gov ID	NCT03535740
Type(s) de cancer	Poumon non à petites cellules
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Traitement
Médicament	Brigatinib
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Scott Owen
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Statut	Actif en recrutement
But étude	The primary purpose of this study is to determine the efficacy of brigatinib by confirmed objective response rate (ORR) by response evaluation criteria in solid tumors (Response Evaluation Criteria in Solid Tumors [RECIST]), in participants with ALK+ locally advanced or metastatic NSCLC whose disease has progressed on therapy with alectinib or ceritinib.
Critères d'éligibilité	• Have histologically or cytologically confirmed stage IIIB (locally advanced or recurrent and not a participant for curative therapy) or stage IV non-small-cell lung cancer (NSCLC). • Must meet both of the following 2 criteria: • Have documentation of anaplastic lymphoma kinase (ALK) rearrangement by a positive result from any laboratory test® approved by the food and drug administration (FDA) or Have documented ALK rearrangement by a different test (non-FDA-approved local lab tests) and have provided tumor sample to the central laboratory. (Note: Central laboratory ALK rearrangement testing results are not required to be obtained before randomization.) • Had been on any one of the ALK tyrosine kinase inhibitor (TKIs) (alectinib, ceritinib, crizotinib) for at least 12 weeks before progression. • Had progressive disease (PD) while on alectinib or ceritinib • Had alectinib or ceritinib as the most recent ALK inhibitor therapy. • Have at least 1 measurable lesion per response evaluation criteria in solid tumors (RECIST) version 1.1 as assessed by the investigator. • Had recovered from toxicities related to prior anticancer therapy to national cancer institute common terminology criteria for adverse events (NCI CTCAE), version 4.03, Grade <=1. (Note: Treatment-related alopecia or peripheral neuropathy that are Grade >1 are allowed if deemed irreversible.) and have adequate major organ functions. • Have a life expectancy of ≥3 months.

Critères d'exclusion	• Had received any prior ALK-targeted TKI other than crizotinib, alectinib, or ceritinib. • Had received both alectinib and ceritinib. • Had previously received more than 3 regimens of systemic anticancer therapy for locally advanced or metastatic disease. • Had symptomatic brain metastasis (parenchymal or leptomeningeal). Participants with asymptomatic brain metastasis or who have stable symptoms that did not require an increased dose of corticosteroids to control symptoms in the past 7 days before the first dose of brigatinib may be enrolled. • Had current spinal cord compression (symptomatic or asymptomatic and detected by radiographic imaging). Participants with leptomeningeal disease and without cord compression are allowed. • Had a cerebrovascular accident or transient ischemic attack within 6 months before first dose of brigatinib. • Had an ongoing or active infection, including, but not limited to, the requirement for intravenous antibiotics. • Had malabsorption syndrome or other gastrointestinal (GI) illness that could affect oral absorption of brigatinib.