Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Étude multicentrique de phase 3, menée sans insu et à répartition aléatoire, évaluant l'efficacité et l'innocuité de l'acalabrutinib (ACP-196) en association avec le vénétoclax combiné ou non à l'obinutuzumab, comparativement à une immunochimiothérapie choisie par l'investigateur chez des sujets atteints d'une leucémie lymphoïde chronique jamais traitée ne présentant pas de délétion 17p ou de mutation du gène TP53
Protocole ID	ACE-CL-311
ClinicalTrials.gov ID	NCT03836261
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Type étude	Traitement
Médicament	Acalabrutinib avec Venetoclax avec/sans Obinutuzumab versus chimiothérapie au choix de l'investigateur
Institution	CIUSSS DU NORD-DE-L'ILE-DE-MONTREAL H HOPITAL DU SACRE-COEUR-DE-MONTREAL 5400 boul. Gouin Ouest, Montréal, QC, H4J1C5
Ville	Montréal
Investigateur principal	Dre Inès Chamakhi
Coordonnateur	Marie-Anne Capobianco 514-338-2222 poste 3493
Statut	Fermé
But étude	The purpose of this study is to evaluate the efficacy and safety of acalabrutinib in combination with venetoclax and acalabrutinib in combination with venetoclax with and without obinutuzumab compared to chemoimmunotherapy in subjects with previously untreated CLL.
Critères d'éligibilité	• Men and women ≥18 years of age. • Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. • Diagnosis of CLL that meets published diagnostic criteria (Hallek et al. 2018) • Active disease per IWCLL 2018 criteria that requires treatment. • Participants must use highly effective birth control throughout the study.
Critères d'exclusion	• Any prior CLL-specific therapies. • Detected del(17p) or TP53 mutation. • Transformation of CLL to aggressive non-Hodgkin lymphoma (NHL) (e.g., Richter's transformation, prolymphocytic leukemia [PLL], or diffuse large B cell lymphoma [DLBCL]), or central nervous system (CNS) involvement by leukemia. • History of confirmed progressive multifocal leukoencephalopathy (PML). • Received any investigational drug within 30 days before first dose of study drug. • Major surgical procedure within 30 days before the first dose of study drug. • Significant cardiovascular disease such as symptomatic arrhythmias, congestive heart failure, or myocardial infarction within 6 months of Screening, or any Class 3 or 4 cardiac disease. Note: Subjects with controlled, asymptomatic atrial fibrillation are allowed to enroll on study. • Malabsorption syndrome, disease significantly affecting gastrointestinal function, or resection of the stomach, or extensive small bowel resection that is likely to affect absorption, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction, or gastric restrictions and bariatric surgery, such as gastric bypass. • Received a live virus vaccination within 28 days of first dose of study drug. • Known history of infection with human immunodeficiency virus (HIV).

- Serologic status reflecting active hepatitis B or C infection.
- History of known hypersensitivity or anaphylactic reactions to study drugs or excipients.
- History of stroke or intracranial hemorrhage within 6 months before first dose of study drug.
- Known bleeding disorders.
- Requires or receiving anticoagulation with warfarin or equivalent vitamin K antagonists.
- Female participants must not be breastfeeding or pregnant.
- Concurrent participation in another therapeutic clinical trial.