Essai Clinique

Généré le 19 avr. 2024 à partir de

Titre	A Phase 3 Open-Label, Randomized Study of Pirtobrutinib (LOXO-305) Versus Ibrutinib in Patients With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Protocole ID	BRUIN-CLL-314
ClinicalTrials.gov ID	NCT05254743
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Type étude	Clinique
Médicament	Pirtobrutinib versus Ibrutinib
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Robert Delage
Coordonnateur	Philippe Nadeau 418-649-0252 poste 63115
Statut	Actif en recrutement
Date d'activation	30-01-2023
But étude	The purpose of this study is to compare the efficacy and safety of pirtobruitinib (LOXO-305) to ibrutinib in participants with CLL/SLL. Participants may or may not have already had treatment for their cancer. Participation could last up to six years.
Critères d'éligibilité	• Confirmed diagnosis of CLL/SLL requiring therapy per iwCLL 2018 criteria • Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2 • Adequate organ function • Platelets greater than or equal to (≥)50 x 10?/liter (L), hemoglobin ≥8 grams/deciliter (g/dL), and absolute neutrophil count ≥0.75 x 10?/L • Kidney function: Estimated creatinine clearance ≥30 milliliters per minute (mL/min)
Critères d'exclusion	• Known or suspected Richter's transformation to diffuse large B-cell lymphoma (DLBCL), prolymphocytic leukemia, or Hodgkin's lymphoma at any time preceding enrollment • Known or suspected central nervous system (CNS) involvement • A significant history of renal, neurologic, psychiatric, endocrine, metabolic or immunologic disease • Active uncontrolled auto-immune cytopenia (e.g., autoimmune hemolytic anemia [AIHA], idiopathic thrombocytopenic purpura [ITP]) • Significant cardiovascular disease • Active hepatitis B or hepatitis C • Active cytomegalovirus (CMV) infection • Active uncontrolled systemic bacterial, viral, or fungal infection • Known human immunodeficiency virus (HIV) infection, regardless of cluster of differentiation 4 (CD4) count • Clinically significant active malabsorption syndrome or other condition likely to affect GI absorption of the oral-administered study treatments • Ongoing inflammatory bowel disease • Prior exposure to BTK inhibitor (covalent or noncovalent)

- Concurrent use of investigational agent or anticancer therapy except hormonal therapy
- Participants requiring therapeutic anticoagulation with warfarin or another Vitamin K antagonist
- Use of ≥ 20 mg prednisone daily or equivalent dose of steroid at the time of first dose of study drug
- Vaccination with a live vaccine within 28 days prior to randomization
- Participants receiving chronic therapy with a strong cytochrome P450 (CYP)3A inhibitor (except posaconazole and voriconazole) which cannot be stopped within 3-5 half lives of the CYP3A inhibitor therapy prior to start of study drug treatment.
- Participants with known hypersensitivity, including anaphylaxis, to any component or excipient of pirtobrutinib or ibrutinib