


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	<a href="https://clinicaltrials.gov/ct2/show/study/NCT05254743">NCT05254743</a>
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	Fermé
Date d'activation	30-01-2023
But étude	The purpose of this study is to compare the efficacy and safety of pirtobrutinib (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	<ul style="list-style-type: none"><li>• Confirmed diagnosis of CLL/SLL requiring therapy per iwCLL 2018 criteria</li><li>• Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2</li><li>• Adequate organ function</li><li>• Platelets greater than or equal to <math>\geq 50 \times 10^9/\text{liter}</math> (L), hemoglobin <math>\geq 8</math> grams/deciliter (g/dL), and absolute neutrophil count <math>\geq 0.75 \times 10^9/\text{L}</math></li><li>• Kidney function: Estimated creatinine clearance <math>\geq 30</math> milliliters per minute (mL/min)</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• Known or suspected Richter's transformation to diffuse large B-cell lymphoma (DLBCL), prolymphocytic leukemia, or Hodgkin's lymphoma at any time preceding enrollment</li><li>• Known or suspected central nervous system (CNS) involvement</li><li>• A significant history of renal, neurologic, psychiatric, endocrine, metabolic or immunologic disease</li><li>• Active uncontrolled auto-immune cytopenia (e.g., autoimmune hemolytic anemia [AIHA], idiopathic thrombocytopenic purpura [ITP])</li><li>• Significant cardiovascular disease</li><li>• Active hepatitis B or hepatitis C</li><li>• Active cytomegalovirus (CMV) infection</li><li>• Active uncontrolled systemic bacterial, viral, or fungal infection</li><li>• Known human immunodeficiency virus (HIV) infection, regardless of cluster of differentiation 4 (CD4) count</li><li>• Clinically significant active malabsorption syndrome or other condition likely to affect GI absorption of the oral-administered study treatments</li><li>• Ongoing inflammatory bowel disease</li><li>• Prior exposure to BTK inhibitor (covalent or noncovalent)</li></ul>

- Concurrent use of investigational agent or anticancer therapy except hormonal therapy
- Participants requiring therapeutic anticoagulation with warfarin or another Vitamin K antagonist
- Use of  $\geq 20$  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