Essai Clinique

Généré le 15 mai 2024 à partir de

Titre	A Phase 3 Open-Label, Randomized Study of Fixed Duration Pirtobrutinib (LOXO-305) Plus Venetoclax and Rituximab Versus Venetoclax and Rituximab in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Protocole ID	BRUIN CLL-322
ClinicalTrials.gov ID	NCT04965493
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Type étude	Clinique
Médicament	Pirtobrutinib (LOXO-305) + venetoclax et rituximab versus venetoclax et rituximab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dre Sonia Skamene
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Statut	Actif en recrutement
Date d'activation	01-05-2023
But étude	The purpose of this study is to compare the efficacy and safety of fixed duration pirtobruitinib (LOXO-305) with VR (Arm A) compared to VR alone (Arm B) in patients with CLL/SLL who have been previously treated with at least one prior line of therapy. Participation could last up to five years.
Critères d'éligibilité	• Confirmed diagnosis of CLL/SLL requiring therapy per iwCLL 2018 criteria • Previous treatment with at least one line of therapy that may include a covalent Bruton's tyrosine kinase (BTK) inhibitor • Platelets greater than or equal to (≥)50 x 10?/liter (L), hemoglobin ≥8 grams/deciliter (g/dL) and absolute neutrophil count ≥1.0 x 10?/L • Adequate organ function • Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2 • Estimated creatinine clearance ≥30 milliliters per minute (mL/min)
Critères d'exclusion	• Known or suspected Richter's transformation at any time preceding enrollment • Prior therapy with a non-covalent (reversible) BTK inhibitor • Patients requiring therapeutic anticoagulation with warfarin or another Vitamin K antagonist • Current treatment with strong cytochrome P450 (CYP) 3A4 (CYP3A4) inhibitors or inducers • Prior therapy with venetoclax • Central nervous system (CNS) involvement • Active uncontrolled systemic bacterial, viral, fungal, or parasitic infection • Known human immunodeficiency virus (HIV) infection, regardless of cluster of differentiation 4 (CD4) count • Allogeneic stem cell transplantation (SCT) or chimeric antigen receptor (CAR)-T within 60 days • Active hepatitis B or hepatitis C • Known active cytomegalovirus (CMV) infection • Uncontrolled immune thrombocytopenic purpura (ITP) or autoimmune hemolytic anemia (AIHA) • Significant cardiovascular disease

- Vaccination with a live vaccine within 28 days prior to randomization
- Patients with the following hypersensitivity:
    - Known hypersensitivity to any component or excipient of pirtobrutinib and venetoclax
    - Prior significant hypersensitivity to rituximab
    - Known allergy to allopurinol and inability to take uric acid lowering agent