Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB-3111) Compared With Venetoclax Plus Obinutuzumab in Patients With Previously Untreated Chronic Lymphocytic Leukemia
Protocole ID	BGB-11417-301
ClinicalTrials.gov ID	NCT06073821
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Type étude	Clinique
Médicament	Sonrotoclax + zanubrutinib comparé à vénétoclax + obinutuzumab
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Jean-François Larouche
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Statut	Actif en recrutement
Date d'activation	19-02-2024
But étude	The main objective of this study is to compare the efficacy of sonrotoclax plus zanubrutinib versus venetoclax plus obinutuzumab in participants with chronic lymphocytic leukemia (CLL). Chronic lymphocytic leukemia is a type of blood cancer that affects people around the world. People with CLL suffer from enlarged lymph nodes, spleen, or liver, or have symptoms like night sweats, weight loss and fever. They have shorter life expectancy compared to healthy people. There is an urgent need for new treatment to prolong participant life and control disease-related symptoms. In this study, participants with CLL, without prior treatment will receive either venetoclax plus obinutuzumab combination treatment that is considered a standard first line treatment or receive sonrotoclax plus zanubrutinib. It is hypothesized that sonrotoclax plus zanubrutinib may be better than venetoclax plus obinutuzumab in treating CLL. The main purpose of this study is to compare the duration the participants live without the CLL getting worse between participants who received venetoclax plus obinutuzumab versus sonrotoclax plus zanubrutinib. Approximately 640 participants will be included in this study around the world. Participants will have equal chance to be allocated to receive either of the treatment combinations.
Critères d'éligibilité	• Treatment-naïve (TN) adults with confirmed diagnosis of CLL which requires treatment • Eastern Cooperative Oncology Group (ECOG) score 0, 1, or 2 • Measurable disease by Computer Tomography/Magnetic Resonance Imaging • Adequate liver function as indicated by aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 2.5 x the institutional upper limits of normal (ULNs) value; serum total bilirubin < 3.0 x ULN • Adequate renal function as defined as creatinine clearance ≥ 50 milliliters per minute
Critères d'exclusion	• Previous systemic treatment for CLL • Known prolymphocytic leukemia or history of, or currently suspected, Richter's transformation • Known central nervous system involvement • History of confirmed progressive multifocal leukoencephalopathy (PML) • Uncontrolled hypertension