Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	A Phase 3, Open-label, Randomized Study to Compare the Efficacy and Safety of Nemtabrutinib Plus Venetoclax Versus Venetoclax Plus Rituximab in Participants With Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Following at Least 1 Prior Therapy
Protocole ID	MK-1026-010 (BELLWAVE-010)
ClinicalTrials.gov ID	NCT05947851
Type(s) de cancer	Leucémie lymphoïde chronique (LLC)
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Nemtabrutinib + vénétoclax versus vénétoclax + rituximab
Institution	CIUSSS DE L'ESTRIE – CENTRE HOSP. UNIV. DE SHERBROOKE HOPITAL FLEURIMONT 3001 12e Avenue Nord, Sherbrooke, QC, J1H 5N4
Ville	
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Statut	Actif en recrutement
But étude	The purpose of this study is to assess the safety and tolerability and to confirm the dose of nemtabrutinib in combination with venetoclax in participants with R/R CLL/SLL. The primary study hypotheses are that the combination of nemtabrutinib plus venetoclax is superior to VR with respect to progression-free survival (PFS) per 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria as assessed by blinded independent central review.
Critères d'éligibilité	• Confirmed diagnosis of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) and active disease clearly documented to initiate therapy. • Deletion (Del) (17p) status, tumor protein 53 (TP53) mutation status, immunoglobulin heavy chain gene (IGHV) mutation status and Bruton's tyrosine kinase (BTK)-C481 mutation status results required before randomization for Part 2 participants only. • Relapsed or refractory to at least 1 prior available therapy. • Have at least 1 marker of disease burden. • Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 within 7 days before randomization. • Has a life expectancy of at least 3 months. • Has the ability to swallow and retain oral medication. • Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV deoxyribonucleic acid (DNA) viral load before randomization. • Participants with history of hepatitis C virus (HCV) infection are eligible if HCV ribonucleic acid (RNA) viral load is undetectable at screening. • Participants with human immunodeficiency virus (HIV) who meet ALL eligibility criteria. • Participants with adequate organ function with specimens collected within 7 days before the start of study intervention. • If capable of producing sperm, participant agrees to eliminate Nemtabrutinib: 12 days, Venetoclax: 1 month (30 days), Rituximab (rituximab biosimilar): not applicable; abstains from penile-vaginal intercourse as their preferred and usual lifestyle; OR uses prescribed contraception.

	• Participant assigned female sex at birth are eligible to participate if not pregnant or breastfeeding and are not a person of childbearing potential (POCBP) OR is a POCBP and uses a contraceptive method that is highly effective, has a negative highly sensitive pregnancy test, and abstains from breastfeeding.
Critères d'exclusion	• Has an active hepatitis B virus/ hepatitis C virus (HBV/HCV) infection. • Has gastrointestinal (GI) dysfunction that may affect drug absorption. • Has a known additional malignancy that is progressing or has required active treatment within the past 3 years. • Has diagnosis of Richter Transformation or active central nervous system (CNS) involvement by CLL/SLL. • Has an active infection requiring systemic therapy, such as intravenous (IV) antibiotics, during screening. • HIV-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease and/or acquired immune deficiency syndrome (AIDS)-defining opportunistic infection in the past 12 months before screening. • Has QT interval corrected (QTc) prolongation or other significant electrocardiogram (ECG) abnormalities. • Has a known allergy/sensitivity to nemtabrutinib or contraindication to venetoclax/rituximab (or rituximab biosimilar), or any of the excipients. • Has history of severe bleeding disorders (eg, hemophilia). • Has received prior systemic anticancer therapy within 5 half-lives or 4 weeks (if prior therapy was a monoclonal antibody) before randomization. • Has received prior B-cell lymphoma 2 inhibitor(s) (BCL2i) including venetoclax or Non-covalent Bruton's tyrosine kinase inhibitor (BTKi). • Is currently being treated with p-glycoprotein (P-gp) substrates with a narrow therapeutic index, cytochrome P450 3A (CYP3A) strong or moderate inducers or CYP3A strong inhibitors. • Has received a live or live attenuated vaccine within 30 days before the first dose of study intervention. • Has received an investigational agent or has used an investigational device within 4 weeks before study intervention administration. • Has a known psychiatric or substance use disorder that would interfere with the participant's ability to cooperate with the requirements of the study. • Participants who have not adequately recovered from major surgery or have ongoing surgical complications.