Essai Clinique

Généré le 16 mai 2025 à partir de

Titre	A Multicenter, Open-label, Phase 2 Basket Study to Evaluate the Safety and Efficacy of MK-2140 as a Monotherapy and in Combination in Participants With Aggressive and Indolent B-cell Malignancies
Protocole ID	MK-2140-006
ClinicalTrials.gov ID	NCT05458297
Type(s) de cancer	Leucémie lymphoïde chronique (LLC) Lymphome non-hodgkinien (LNH)
Phase	Phase II
Type étude	Clinique
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Statut	Actif en recrutement
Date d'activation	30-07-2023
But étude	The purpose of this study is to assess the safety and tolerability of zilovertamab vedotin as monotherapy and in combination in participants with select B-cell lymphomas including mantle cell lymphoma (MCL), Richter's transformation lymphoma (RTL), follicular lymphoma (FL), and chronic lymphocytic leukemia (CLL). This study will also evaluate zilovertamab vedotin as monotherapy and in combination with respect to objective response rate. • Cohort A: Participants with relapsed or refractory MCL relapsed or refractory disease after at least 2 prior systemic therapies including a Bruton's tyrosine kinase inhibition/inhibitor (BTKi), and post therapy chimeric antigen receptor T (CAR-T) cell therapy or ineligible for CAR-T cell therapy • Cohort B: Participants with relapsed or refractory RT disease after at least 1 prior systemic therapy • Cohort C: Participants with relapsed or refractory MCL relapsed or refractory disease after at least 1 prior systemic therapy and no prior exposure to a non-covalent BTKi • Cohort D: Participants with relapsed or refractory FL and CLL relapsed or refractory disease after at least 2 prior systemic therapies and have no other available therapy • Cohort E: Participants with relapsed or refractory FL after at least 2 prior systemic therapies and have no other available therapy • Cohort F: Participants with relapsed or refractory CLL after at least 2 prior systemic therapies and have no other available therapy The primary study hypothesis is that zilovertamab vedotin monotherapy has an increased Objective Response Rate (ORR) per Lugano Response Criteria as assessed by blinded independent central review (BICR).
Critères d'éligibilité	• For aggressive B-cell malignancies MCL: Has histologically confirmed biopsy according to the 2016 World Health Organization (WHO) classification of neoplasms of the hematopoietic and lymphoid tissues and has relapsed or refractory disease after at least 2 prior systemic therapies including a Bruton's tyrosine kinase inhibition/inhibitor(s) (BTKi), and is post chimeric antigen receptor T (CAR-T) cell therapy or is ineligible for CAR-T cell therapy. • For aggressive B-cell malignancies MCL Cohort C: Has histologically confirmed biopsy according to the 2016 World Health Organization (WHO) classification of neoplasms of the hematopoietic and lymphoid tissues and has relapsed or refractory disease after at least 1 prior

	systemic therapy and has no prior exposure to a non-covalent BTKi. • For aggressive B-cell malignancies Richter transformation lymphoma (RTL): Has histologically confirmed biopsy according to the 2016 World Health Organization (WHO) classification of neoplasms of the hematopoietic and lymphoid tissues and has relapsed or refractory disease. • For indolent B-cell malignancies FL and CLL: Has histologically confirmed biopsy and has relapsed or refractory disease after at least 2 prior systemic therapies and no other available therapy. • 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 viral load prior to randomization/allocation. • Have an ECOG performance status of 0 to 2 assessed within 7 days before cycle 1 day 1.
Critères d'exclusion	• Has received solid organ transplant at any time. • Has clinically significant (ie, active) cardiovascular disease: cerebral vascular accident/stroke (<6 months prior to enrollment), myocardial infarction (<6 months prior to enrollment), unstable angina (<6 months prior to enrollment), congestive heart failure (New York Heart Association Classification Class ≥II), or serious cardiac arrhythmia requiring medication. • Has pericardial effusion or clinically significant pleural effusion. • Has ongoing Grade >1 peripheral neuropathy. • Has a demyelinating form of Charcot-Marie-Tooth disease. • Has a history of a second malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years. • Participants with FL who have transformed to a more aggressive type of lymphoma. • Has received prior systemic anticancer therapy within 5 half-lives or 4 weeks (if prior therapy was a monoclonal antibodies) or 2 weeks (if prior therapy was small molecules like kinase inhibitors) prior to the first dose of study intervention. • Has received prior radiotherapy within 28 days of start of study intervention. Participants must have recovered from all radiation-related toxicities. • Has ongoing corticosteroid therapy exceeding 30 mg daily of prednisone equivalent. • Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. • Has known active central nervous system (CNS) lymphoma involvement or active CNS involvement by lymphoma. • Has an active infection requiring systemic therapy. • Has a known history of human immunodeficiency virus (HIV) infection. • Active HBV or hepatitis C virus (HCV) infection. • For Cohort C only: has any clinically significant gastrointestinal abnormalities that might alter absorption.