Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	A Phase 2 Study to Evaluate the Efficacy and Safety of MK-1026 in Participants With Hematologic Malignancies
Protocole ID	MK-1026-003
ClinicalTrials.gov ID	NCT04728893
Type(s) de cancer	Leucémie lymphoïde chronique (LLC) Lymphome non-hodgkinien (LNH)
Phase	Phase II
Type étude	Clinique
Médicament	Nemtabrutinib
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
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Statut	Fermé
Date d'activation	01-01-2022
But étude	The purpose of this study is to evaluate the safety and efficacy of nemtabrutinib (formerly ARQ 531) in participants with hematologic malignancies of chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL), Richter's transformation, marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), follicular lymphoma (FL), and Waldenström's macroglobulinemia (WM).This study will be performed in 2 parts: Dose Escalation and Confirmation (Part 1) and Cohort Expansion (Part 2). Following determination of a recommended phase 2 dose (RP2D) in Part 1, the study plans to proceed with Part 2 using 8 disease-specific expansion cohorts (Cohorts A to H).
Critères d'éligibilité	• Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 within 7 days prior to allocation • Has a life expectancy of at least 3 months, based on the investigator assessment • 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 viral load prior to randomization • Participants with history of Hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening • Has adequate organ function • Male participants agree to refrain from donating sperm and agree to either remain abstinent from heterosexual intercourse as their preferred and usual lifestyle OR agree to use contraception, during the intervention period and for 12 days after last dose of study intervention • Female participants not pregnant or breastfeeding are eligible to participate if not a woman of childbearing potential (WOCBP), or if a WOCBP they either use a contraceptive method that is highly effective OR remain abstinent from heterosexual intercourse as their preferred and usual lifestyle during the intervention period and for at least 30 days after the last dose of study intervention **Part 1 and Part 2 (Cohorts A to C and Cohort I)**

	• Has a confirmed diagnosis of CLL/SLL
	  • Has active disease for CLL/SLL clearly documented to initiate therapy
	  • Has evaluable core or excisional lymph node biopsy for biomarker analysis from an archival or newly obtained biopsy at Screening (optional for participants enrolling in Part 1)
	Part 2 (Cohorts D to G)
	• Has a confirmed diagnosis of and response to previous treatment of one of the following:
	  • Participants with Richter's transformation who are relapsed or refractory following at least 1 line of prior therapy (Cohort D)
	  • Participants with pathologically confirmed MCL, documented by either overexpression of cyclin D1 or t(11;14), who are relapsed or are refractory to chemoimmunotherapy and a covalent irreversible BTK inhibitor (BTKi) (Cohort E)
	  • Participants with MZL (including splenic, nodal, and extra nodal MZL) who are relapsed or refractory to chemoimmunotherapy and a covalent irreversible BTKi (Cohort F)
	  • Participants with FL who are relapsed or refractory to chemoimmunotherapy, immunomodulatory agents (i.e. lenalidomide plus rituximab) (Cohort G)
	• Have measurable disease defined as at least 1 lesion that can be accurately measured in at least 2 dimensions with spiral CT scan
	• Has a lymph node biopsy for biomarker analysis from an archival or newly obtained biopsy at Screening
	Part 2 (Cohort H): confirmed diagnosis of WM; participants who are relapsed or refractory to standard therapies for WM including chemoimmunotherapy and a covalent irreversible BTKi
	• Has active disease defined as 1 of the following: systemic symptoms, physical findings, laboratory abnormalities, coexisting disease
	• Has measurable disease, satisfying any of the following: at least 1 lesion that can be accurately measured in at least 2 dimensions with spiral CT scan (minimum measurement must be >15 mm in the longest diameter or >10 mm in the short axis); IgM ≥450 mg/dL; or bone marrow infiltration of 10%
	• Has fresh bone marrow aspirate or a lymph node biopsy for biomarker analysis at Screening or a lymph node biopsy from an archival

Critères d'exclusion	• Has active HBV/HCV infection (Part 1 and Part 2) • Has a history of malignancy ≤3 years prior to providing documented informed consent except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer • Has active central nervous system (CNS) disease • Has an active infection requiring systemic therapy • Has a known history of human immunodeficiency virus (HIV) infection • Has received prior systemic anti-cancer therapy within 4 weeks prior to allocation • Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study intervention • Has any clinically significant gastrointestinal abnormalities that might alter absorption