Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	A Phase 1 Study of Oral LY3410738 in Patients With Advanced Hematologic Malignancies With IDH1 or IDH2 Mutations
Protocole ID	LOXO-IDH-20001
ClinicalTrials.gov ID	NCT04603001
Type(s) de cancer	Leucémie myéloïde aiguë (LMA) Syndrome myélodysplasique
Phase	Phase I
Type étude	Clinique
Médicament	LY3410738
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 Sarit Assouline
Coordonnateur	
Statut	Actif en recrutement
But étude	This study includes 2 parts: dose escalation and dose expansion. The dose escalation will enroll eligible patients with select IDH-mutant advanced hematologic malignancies. Once the maximum tolerated dose (MTD) and/or recommended Phase 2 dose (RP2D) of LY3410738 is established, the dose expansion will begin and enroll into 4 cohorts to further evaluate safety and clinical activity
Critères d'éligibilité	• Advanced IDH mutant hematologic malignancy • Patients must have received prior therapy • Blasts at least 5% in bone marrow. • Patients must have a qualifying IDH1 R132, IDH2 R140 or IDH2 R172 mutation • Eastern Cooperative Oncology Group (ECOG) 0-2 • Adequate organ function • Ability to swallow capsules • Ability to comply with outpatient treatment, laboratory monitoring, and required clinic visits for the duration of study participation • Willingness of men and women of reproductive potential to observe conventional and effective birth control for the duration of treatment and for 3 months following the last dose of study treatment.
Critères d'exclusion	• Investigational agent or anticancer therapy within 2 weeks or 5 half-lives, whichever is shorter; or investigational monoclonal antibody within 4 weeks prior to planned start of LY3410738 • Major surgery within 4 weeks prior to planned start of LY3410738. • Active, uncontrolled clinically significant systemic bacterial, viral, fungal or parasitic infection or an unexplained fever > 38.5ºC during screening or on the first day of study drug administration. • Another concurrent malignancy requiring active therapy. • Active central nervous system involvement • Any unresolved toxicities from prior therapy greater than CTCAE v5.0 Grade 2 at the time of starting study treatment except for alopecia. • History of hematopoietic stem cell transplant (HSCT) or CAR-T therapy within 60 days of the first dose of LY3410738 • Clinically significant cardiovascular disease • Active hepatitis B (HBV)

- Active hepatitis C virus (HCV)
- Clinically significant active malabsorption syndrome or other condition likely to affect gastrointestinal (GI) absorption of the study drug
- Current treatment with certain strong cytochrome P450 3A4 (CYP3A4) inhibitors or inducers and/or strong p-gp inhibitor, with the exception of patients being treated with allowed antifungal inhibitors of CYP3A4
- Treatment with proton pump inhibitor (PPIs) within 7 days of starting LY3410738
- Any serious underlying medical or psychiatric condition (e.g. alcohol or drug abuse), dementia or altered mental status or any issue that would impair the ability of the patient to understand informed consent or that in the opinion of the investigator would contraindicate the patient's participation in the study or confound the results of the study
- Known human immunodeficiency virus (HIV), excluded due to potential drug-drug interactions between anti-retroviral medications and LY3410738
- Pregnancy, lactation or plan to breastfeeding during the study or within 30 days of the last dose of study intervention
- Known hypersensitivity to any of the components of LY3410738 or its formulation