Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	Étude multicentrique ouverte de phase 1 visant à évaluer l'innocuité, la pharmacocinétique et la pharmacodynamique du H3B-6527 chez des sujets atteints d'un carcinome hépatocellulaire avancé ou d'un cholangiocarcinome intrahépatique.
Protocole ID	H3B-6527
ClinicalTrials.gov ID	NCT02834780
Type(s) de cancer	Foie
Phase	Phase I
Stade	Maladie avancée ou métastatique
Médicament	H3B-6527
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
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Statut	Fermé
But étude	The purpose of this study is to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of H3B-6527, and to assess the safety, tolerability and pharmacokinetics of H3B-6527.
Critères d'éligibilité	• Participants with hepatocellular carcinoma (HCC) or intrahepatic cholangiocarcinoma (ICC). • Must have had at least one prior standard-of-care therapy, unless contraindicated. • Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. • Must be willing to undergo a biopsy prior to treatment and on Cycle 2 Day 1 (Part 2 only). • Adequate bone marrow and organ function.
Critères d'exclusion	• Uncontrolled significant active infections, except Hepatitis B (HBV) or Hepatitis C (HCV). • Known human immunodeficiency virus (HIV) infection. • Presence of gastric or esophageal varices requiring active treatment. • Previous treatment with selective FGF19-FGFR4 targeted therapy. • Females of childbearing potential, or males who have not had a successful vasectomy, who are unable or unwilling to follow adequate contraceptive measures.