Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	An Exploratory Phase 1/2 Open-Label Multi-Arm Trial to Evaluate the Safety and Efficacy of CC-90009 Combinations in Subjects With Acute Myeloid Leukemia
Protocole ID	CC-90009-AML-002
ClinicalTrials.gov ID	NCT04336982
Type(s) de cancer	Leucémie myéloïde aiguë (LMA)
Phase	Phase I-II
Type étude	Clinique
Médicament	CC-90009
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
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But étude	CC-90009-AML-002 is an exploratory Phase 1b open-label multi-arm trial to evaluate the safety and efficacy of CC-90009 in combination with anti-leukemia agents in subjects with acute myeloid leukemia (AML).Study CC-90009-AML-002 is an open-label, multi-arm, parallel multi-cohort, multicenter, Phase 1b study to determine the safety, tolerability, PK, and efficacy of CC 90009 in combination with anti-leukemia agents used for the treatment of AML. CC 90009 will be given as a combination therapy to subjects with newly diagnosed (ND) or relapsed or refractory (R/R) AML. The dose and schedule finding part (Part A) of the study will evaluate the safety, PK and PD data, and preliminary efficacy information and determine the Part B dose and schedule for each arm.The expansion part (Part B) of the study will further evaluate the safety and efficacy of the CC-90009 containing combination at or below the maximum tolerated dose (MTD) in the selected cohorts in order to determine the recommended Phase 2 dose (RP2D) for subjects with AML.

Critères d'éligibilité	• Adult subject must understand and voluntarily sign an ICF prior to any study-related assessments/procedures being conducted.
	• Arm A (CC-90009 + venetoclax/azacitidine):
	  • Newly diagnosed AML and is ≥ 75 years of age or intensive chemotherapy ineligible OR
	  • Refractory AML and is ≥ 18 years of age
	• Arm B (CC-90009 + gilteritinib):
	  • Subject is ≥ 18 years of age.
	  • FLT3-ITD positive relapsed or refractory AML.
	  • Gilteritinib treatment naïve
	• Subject has Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2.
	• Subject must have the following screening laboratory values:
	  • Total White Blood Cell count (WBC) < 25 x 10^9 prior to study treatments. Treatment with hydroxyurea to achieve this level is allowed.
	  • Selected electrolytes within normal limits or correctable with supplements.
	  • Participant must have adequate liver function as demonstrated by: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 2.5 x upper limit of normal (ULN) and bilirubin ≤ 1.5 x ULN
	  • Participant has adequate renal function as demonstrated by an estimated serum creatinine clearance of ≥ 60 mL/min using the Cockcroft-Gault equation.
	• Agree to follow the CC-90009 Pregnancy Prevention Plan (PPP) and combination agents'

	requirements.

Critères d'exclusion	• Subject with acute promyelocytic leukemia (APL)
	• Subject has received systemic anticancer therapy (including investigational therapy) or radiotherapy < 28 days or 5 half-lives, whichever is shorter, prior to the start of study treatment
	• Patients with prior autologous hematopoietic stem cell transplant (HSCT) who, in the investigator's judgment, have not fully recovered from the effects of the last transplant (eg, transplant related side effects)
	• Prior allogeneic HSCT with either standard or reduced intensity conditioning ≤ 6 months prior to dosing
	• Subject on systemic immunosuppressive therapy post HSCT at the time of screening, or with clinically significant graft-versus-host disease (GVHD). The use of topical steroids for ongoing skin or ocular GVHD is permitted
	• Subject has persistent, clinically significant non-hematologic toxicities from prior therapies which have not recovered to < Grade 2
	• Subject has or is suspected of having central nervous system (CNS) leukemia. Evaluation of cerebrospinal fluid is only required if CNS involvement by leukemia is suspected during screening.
	• Disorders or conditions disrupting normal calcium homeostasis or preventing calcium supplementation.
	• Impaired cardiac function or clinically significant cardiac diseases, including any of the following:
	  • Left ventricular ejection fraction (LVEF) < 45% as determined by multiple gated acquisition (MUGA) scan or echocardiogram (ECHO).
	  • Complete left bundle branch or bifascicular block.
	  • Congenital long QT syndrome.
	  • Persistent or clinically meaningful ventricular arrhythmias.
	  • QTcF ≥ 470 ms (Arm A) or > 450 ms (Arm B) on Screening electrocardiogram (ECG)
	  • Unstable angina pectoris or myocardial infarction ≤ 6 months prior to starting study treatments or unstable arrhythmia.
	  • Cardiovascular disability status of New York Heart Association Class ≥2. Class 2 is defined as cardiac disease in which patients are comfortable at rest but ordinary physical activity results in fatigue, palpitations, dyspnea, or anginal pain.
	• Subject is a pregnant or lactating female
	• Additional exclusion criteria based on combination agent: a. For Combination Arm A (venetoclax/azacitidine):
	  • Received strong or moderate CYP3A inhibitors or inducers or P-gp inhibitors within 7 days prior to initiation of first venetoclax dose.
	  • Subject has consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges), or Star fruit within 3 days prior to first venetoclax dose through last dose of venetoclax.
	• Previous SARS-CoV-2 infection within 10 days for mild or asymptomatic infections or 20 days for severe/critical illness prior to C1D1a. Acute symptoms must have resolved and based on investigator assessment in consultation with the medical monitor, there are no sequelae that would place the participant at a higher risk of receiving study treatment.
	• Previous SARS-CoV-2 vaccine within 14 days of C1D1.