Essai Clinique

Généré le 18 mai 2024 à partir de

Titre	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Magrolimab Versus Placebo in Combination With Venetoclax and Azacitidine in Newly Diagnosed, Previously Untreated Patients With Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy
Protocole ID	ENHANCE-3
ClinicalTrials.gov ID	NCT05079230
Type(s) de cancer	Leucémie myéloïde aiguë (LMA)
Phase	Phase III
Type étude	Clinique
Médicament	Magrolimab versus placebo en association avec venetoclax et azacitidine
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
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Statut	Actif en recrutement
Date d'activation	24-07-2023
But étude	The goal of this clinical study is to compare the study drugs, magrolimab + venetoclax + azacitidine, versus placebo + venetoclax + azacitidine in participants with untreated acute myeloid leukemia (AML) who are not able to have chemotherapy.

Critères d'éligibilité	• Previously untreated individuals with histological confirmation of acute myeloid leukemia (AML) by World Health Organization (WHO) criteria who are ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age, or comorbidity. Individuals must be considered ineligible for intensive chemotherapy, defined by the following:
	  • ≥ 75 years of age; Or
	  • ≥ 18 to 74 years of age with at least 1 of the following comorbidities:
	  • Eastern Cooperative Oncology Group (ECOG) performance status of 2 or 3
	  • Diffusing capacity of the lung of carbon monoxide ≤ 65% or forced expiratory volume in 1 second ≤ 65%
	  • Left ventricular ejection fraction ≤ 50%
	  • Baseline creatinine clearance ≥ 30 mL/min to < 45 mL/min calculated by the Cockcroft Gault formula or measured by 24-hour urine collection
	  • Hepatic disorder with total bilirubin > 1.5 x upper limit of normal (ULN)
	  • Any other comorbidity that the investigator judges to be incompatible with intensive chemotherapy
	  • ECOG performance status:
	  • Of 0 to 2 for individuals ≥ 75 years of age Or
	  • Of 0 to 3 for individuals ≥ 18 to 74 years of age
	• Individuals with white blood cell (WBC) count ≤ 20 x 10^3/µL prior to randomization. If the individual's WBC is > 20 x10^3/µL prior to randomization, the individual can be enrolled, assuming all other eligibility criteria are met. However, the WBC should be ≤ 20 x 10^3/µL prior to the first dose of study treatment and prior to each magrolimab/placebo dose during Cycle 1.
	  • Note: Individuals can be treated with hydroxyurea and/or leukapheresis prior to

	randomization and throughout the study to reduce the WBC to ≤ 20 x 10^3/μL to enable eligibility for study drug dosing • Hemoglobin must be ≥ 9 g/dL prior to initial dose of study treatment • Note: Transfusions are allowed to meet hemoglobin eligibility • Pretreatment blood cross-match completed

Critères d'exclusion	• Prior treatment with any of the following:
	  • cluster of differentiation 47 (CD47) or signal regulatory protein alpha (SIRPα)-targeting agents
	  • Antileukemic therapy for the treatment of AML (eg, hypomethylating agents (HMAs), low-dose cytarabine, and/or venetoclax), excluding hydroxyurea
	  • Note: Individuals with prior MDS who have not received prior HMAs or venetoclax or chemotherapeutic agents for MDS may be enrolled in the study. Prior treatment with myelodysplastic syndrome (MDS) therapies including, but not limited to lenalidomide, erythroid-stimulating agents, or similar red blood cell negative (RBC-), white blood cell negative (WBC-), or platelet-direct therapies or growth factors is allowed for these individuals.
	• Clinical suspicion of or documented active central nervous system (CNS) involvement with AML
	• Individuals who have acute promyelocytic leukemia
	• Second malignancy, except MDS, treated basal cell or localized squamous skin carcinomas, localized prostate cancer, or other malignancies for which individuals are not on active anticancer therapies and have had no evidence of active malignancy for at least 1 year