Essai Clinique

Généré le 25 avr. 2024 à partir de

Titre	An Open-label, Multicenter, Phase 1b Study of JNJ-74494550 (Cusatuzumab; Anti-CD70 Monoclonal Antibody) in Combination With Background Therapy for the Treatment of Subjects With Acute Myeloid Leukemia
Protocole ID	ELEVATE
ClinicalTrials.gov ID	NCT04150887
Type(s) de cancer	Leucémie myéloïde aiguë (LMA)
Phase	Phase I
Type étude	Traitement
Médicament	Cusatuzumab + Azacitidine vs Cusatuzumab + Venetoclax vs Cusatuzumab + Venetoclax + Azacitidine
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL H SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr John Storring
Coordonnateur	Henry Nchienzia 514-934-1934 poste 34616
Statut	Fermé
But étude	The purpose of the study is to characterize safety and tolerability of cusatuzumab in combination with various therapies used to treat acute myeloid leukemia (AML).
Critères d'éligibilité	• Diagnosis of acute myeloid leukemia (AML) according to World Health Organization 2016 criteria . Participants with acute promyelocytic leukemia (APL) with t (15;17) or its molecular equivalent (promyelocytic leukemia/retinoic acid receptor alpha [PML RAR alpha]) are not eligible • Must be ineligible for intensive chemotherapy • De novo or secondary AML • Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 • Previously untreated AML except: emergency leukapheresis, hydroxyurea, and/or 1 dose 1-2 gram per meter square (g/m^2) cytarabine during the Screening Phase to control hyperleukocytosis. These treatments must be discontinued greater than or equal to (>=) 24 hours prior to start of study drug. Empiric all trans retinoic acid (ATRA) treatment for presumed acute promyelocytic leukemia (APL) is permitted but APL must be ruled out and ATRA must be discontinued >=24 hours prior to the start of study drug • Contraceptive use by men or women should be consistent with local regulations regarding the use of contraceptive methods for participants participating in clinical studies
Critères d'exclusion	• Leukemic involvement of the central nervous system • Eligible for an allogeneic hematopoietic stem cell transplantation at study entry • Received a live, attenuated vaccine within 4 weeks prior to initiation of study drug • A history of human immunodeficiency virus (HIV) antibody positive or tests positive for HIV if tested at screening • Known allergies, hypersensitivity, or intolerance to cusatuzumab, venetoclax, azacitidine, or their excipients (example: mannitol, an excipient of azacitidine)