Essai Clinique

Généré le 06 mai 2024 à partir de

Titre	A Randomized, Phase 3, Open Label Study Evaluating Subcutaneous Versus Intravenous Administration of Isatuximab in Combination With Pomalidomide and Dexamethasone in Adult Patients With Relapsed and/or Refractory Multiple Myeloma
Protocole ID	EFC15951
ClinicalTrials.gov ID	NCT05405166
Type(s) de cancer	Myélome
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Isatuximab SC versus IV, avec pomalidomide et dexaméthasone
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dr Richard Leblanc
Coordonnateur	
Statut	Actif en recrutement
Date d'activation	08-12-2022
But étude	This is a randomized, multicenter, Phase 3, open-label study evaluating subcutaneous (SC) vs intravenous (IV) administration of isatuximab in combination with pomalidomide and dexamethasone (Pd) in RRMM patients (study participants) who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor (PI). Eligible participants will be randomized 1:1 into 1 of 2 study arms:Arm SC: Isatuximab SC + Pd Arm IV: Isatuximab IV + Pd Participants will be allowed to continue therapy until disease progression, unacceptable adverse events (AEs), participant request to discontinue therapy or any other reason, whichever comes first.
Critères d'éligibilité	• Participants with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor, and with measurable serum M-protein (≥ 0.5 g/dL) and/or urine M-protein (≥ 200 mg/24 hours) and/or serum free light chain (FLC) assay (Involved FLC assay ≥10 mg/dL and abnormal serum FLC ratio (<0.26 or >1.65))
Critères d'exclusion	• Participants less than 18 years old, participants with Eastern Cooperative Oncology Group performance status more than 2 • Primary refractory multiple myeloma participants • Participants refractory to anti-CD38 with a wash-out period inferior to 9 months or intolerant to anti-CD38 mAb agents • Prior therapy with pomalidomide • Participants with inadequate biological tests. • Significant cardiac dysfunction • Participants diagnosed or treated for another cancer within 3 years prior to randomization with the exception of complete resection of basal cell carcinoma or squamous cell carcinoma of the skin, and in situ malignancy, or low risk prostate cancer after curative therapy • Concomitant plasma cell leukemia • Active primary amyloid-light (AL) amyloidosis

- Known acquired immunodeficiency syndrome (AIDS)-related illness or known human immunodeficiency virus (HIV) disease requiring antiviral treatment
- Know active Hepatitis A infection. Current active or chronic hepatitis B (HBV) or hepatitis C (HCV) infection. Participants with chronic HBV or HCV disease that is controlled under antiviral therapy are allowed.
- Women of childbearing potential or male participant with women of childbearing potential who do not agree to use highly effective method of birth control

The above information is not intended to contain all considerations relevant to a participant's potential participation in a clinical trial