Essai Clinique

Généré le 08 mai 2024 à partir de

Titre	An open-label, multicenter, non-randomized phase 2 study of elranatamab monotherapy in participants with multiple myeloma who are refractory to at least one proteasome inhibitor, one immunomodulatory drug and one anti-CD38 antibody
Protocole ID	MagnetisMM-3
ClinicalTrials.gov ID	NCT04649359
Type(s) de cancer	Myélome
Phase	Phase II
Type étude	Clinique
Médicament	Elranatamab
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
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Statut	Fermé
But étude	The purpose of the study is to evaluate whether single-agent Elranatamab (PF-06863135) can provide clinical benefit in participants with relapsed/refractory multiple myeloma. Elranatamab is a bispecific antibody: binding of Elranatamab to CD3-expressing T-cells and BCMA-expressing multiple myeloma cells causes targeted T-cell-mediated cytotoxicity.
Critères d'éligibilité	• Diagnosis of multiple myeloma (IMWG criteria, Rajkumar et al, 2014) • Measurable disease, as defined by at least 1 of the following: 1. Serum M-protein >0.5 g/dL by SPEP 2. Urinary M-protein excretion >200 mg/24 hours by UPEP 3. Serum immunoglobulin FLC≥10 mg/dL (≥100 mg/L) AND abnormal serum immunoglobulin kappa to lambda FLC ratio • Refractory to at least one IMiD • Refractory to at least one PI • Refractory to at least one anti-CD38 antibody • Relapsed/refractory to last anti-myeloma regimen • Cohort A: has not received prior BCMA-directed therapy • Cohort B: has received prior BCMA-directed therapy (ADC or CAR T cells) • ECOG performance status ≤2 • Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade ≤1 • Not pregnant and willing to use contraception
Critères d'exclusion	• Smoldering multiple myeloma • Active Plasma cell leukemia • Amyloidosis • POEMS syndrome • Stem cell transplant within 12 weeks prior to enrollment • Active HBV, HCV, SARS-CoV2, HIV, or any active, uncontrolled bacterial, fungal, or viral infection • Any other active malignancy within 3 years prior to enrollment, except for adequately treated basal cell or squamous cell skin cancer, or carcinoma in situ.

- Previous administration with an investigational drug within 30 days or 5 half-lives preceding the first dose of study intervention used in this study (whichever is longer)