Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Randomized, 2-Arm, Phase 3 Study of Elranatamab Versus Lenalidomide in Patients With Newly Diagnosed Multiple Myeloma Who Are Minimal Residual Disease-Positive After Undergoing Autologous Stem-Cell Transplantation
Protocole ID	MagnetisMM-7 (C1071007)
ClinicalTrials.gov ID	NCT05317416
Type(s) de cancer	Myélome
Phase	Phase III
Type étude	Clinique
Médicament	Elranatamab versus lénalidomide
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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Investigateur principal	Dr Richard Leblanc
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Statut	Actif en recrutement
But étude	The purpose of this study is to evaluate whether elranatamab monotherapy can provide clinical benefit compared to lenalidomide monotherapy (control) in participants with newly diagnosed multiple myeloma who are MRD-positive after undergoing autologous stem cell transplant. Participants in the study will either receive elrantamab as an injection under the skin at the study clinic or lenalidomide orally once daily at home. Participants who will receive elranatamab will start receiving one dose every week after the initial step-up doses. After 6 months of treatment, the frequency of clinic visits for injections will decrease to every other week. Participation in the study will be approximately five years.
Critères d'éligibilité	• Diagnosis of MM as defined according to IMWG criteria (Rajkumar, 2014) with measurable disease at diagnosis History of induction therapy for newly diagnosed MM, followed by high dose therapy and autologous stem cell transplant. Randomization must occur within 120 days from the stem cell transplant. For participants who receive consolidation therapy after ASCT, randomization must occur within 60 days of consolidation and within 7 months from ASCT. • Partial Response or better according to IMWG criteria at the time of randomization • MRD positive (≥10^-5) at screening by central laboratory NGS test (ClonoSEQ assay) Must have an archival bone marrow aspirate sample(s) that identified the dominant malignant (index) clone that is used to track MRD status. This sample sample should preferably be collected before induction treatment (eg, at diagnosis) or before transplant. • ECOG performance status ≤1 • Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade ≤ 1 • Not pregnant and willing to use contraception
Critères d'exclusion	• Plasma cell leukemia • Amyloidosis, Waldenström's macroglobulinemia • POEMS syndrome • Known active CNS involvement or clinical signs of myelomatous meningeal involvement • Previous MM maintenance treatment • Prior treatment with BCMA targeted therapy • 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

- Active, uncontrolled bacterial, fungal, or viral infection, including (but not limited to) HBV, HCV, and known HIV or AIDS-related illness
- Previous administration with an investigational drug or vaccine within 30 days (or as determined by the local requirement) or 5 half-lives preceding the first dose of study intervention used in this study (whichever is longer)