Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	A Multicenter, Open-Label, Randomized Phase III Study to Evaluate the Efficacy and Safety of the Combination of Belantamab Mafodotin, Bortezomib, and Dexamethasone (B-Vd) Compared With the Combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in Participants With Relapsed/Refractory Multiple Myeloma
Protocole ID	DREAMM 7
ClinicalTrials.gov ID	NCT04246047
Type(s) de cancer	Myélome
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Belantamab mafodotin, bortézomib et dexaméthasone (B-Vd) versus daratumumab, bortézomib et dexaméthasone (D-Vd)
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Vincent Laroche
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Statut	Fermé
But étude	This is a phase 3, randomized, open-label study designed to evaluate safety and efficacy of belantamab mafodotin in combination with bortezomib/dexamethasone (Arm A) versus daratumumab in combination with bortezomib/dexamethasone (Arm B) in the participants with relapsed recurrent multiple myeloma.
Critères d'éligibilité	• Confirmed diagnosis of multiple myeloma as defined by the International Myeloma Working Group (IMWG) criteria. • Previously treated with at least 1 prior line of multiple myeloma (MM) therapy, and must have documented disease progression during or after their most recent therapy. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. • Must have at least 1 aspect of measurable disease, defined as one of the following; 1. Urine M-protein excretion >=200 mg per 24-hour, or 2. Serum M-protein concentration >=0.5 grams per deciliter (g/dL), or 3. Serum free light chain (FLC) assay: involved FLC level >=10 mg per dL (>=100 mg per liter) and an abnormal serum free light chain ratio (<0.26 or >1.65). • All prior treatment-related toxicities (defined by National Cancer Institute Common Toxicity Criteria for Adverse Events [NCI-CTCAE] version 5.0) must be <=Grade 1 at the time of enrollment, except for alopecia. • Adequate organ function

Critères d'exclusion	• Intolerant to daratumumab. • Refractory to daratumumab or any other anti-CD38 therapy (defined as progressive disease during treatment with anti-CD38 therapy, or within 60 days of completing that treatment). • Intolerant to bortezomib, or refractory to bortezomib (defined as progressive disease during treatment with a bortezomib-containing regimen of 1.3 mg/m^2 twice weekly, or within 60 days of completing that treatment). Note: participants with progressive disease during treatment with a weekly bortezomib regimen are allowed. • Ongoing Grade 2 or higher peripheral neuropathy or neuropathic pain. • Prior treatment with anti-B-cell maturation antigen (anti-BCMA) therapy. • Prior allogenic stem cell transplant. • Any serious and/or unstable pre-existing medical, psychiatric disorder or other conditions, including renal, liver, cardiovascular, or certain prior malignancies. • Corneal epithelial disease.