Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Phase 3 Randomized Study Comparing Teclistamab in Combination With Daratumumab SC and Lenalidomide (Tec-DR) and Talquetamab in Combination With Daratumumab SC and Lenalidomide (Tal-DR) Versus Daratumumab SC, Lenalidomide, and Dexamethasone (DRd) in Participants With Newly Diagnosed Multiple Myeloma Who Are Either Ineligible or Not Intended for Autologous Stem Cell Transplant as Initial Therapy
Protocole ID	MajesTEC-7
ClinicalTrials.gov ID	NCT05552222
Type(s) de cancer	Myélome
Phase	Phase III
Type étude	Clinique
Médicament	Teclistamab avec daratumumab SC et lénalidomide (Tec-DR) versus talquetamab avec daratumumab SC et lénalidomide (Tal-DR) versus Daratumumab SC, lénalidomide, et dexaméthasone (DRd))
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Marc Lalancette
Coordonnateur	Patricia Chabot 415-525-4444 poste 15768
Statut	Actif en recrutement
Date d'activation	12-08-2024
But étude	The purpose of this study is to compare the efficacy of teclistamab in combination with daratumumab and lenalidomide (Tec-DR) and talquetamab in combination with daratumumab and lenalidomide (Tal-DR) versus daratumumab, lenalidomide, dexamethasone (DRd).
Critères d'éligibilité	• Have a diagnosis of multiple myeloma according to the International Myeloma Working Group (IMWG) diagnostic criteria • Be newly diagnosed and not considered a candidate for high-dose chemotherapy with autologous stem cell transplant (ASCT) due to: ineligible due to advanced age OR; ineligible due to the presence of comorbid condition(s) likely to have a negative impact on tolerability of high-dose chemotherapy with ASCT OR; deferral of high-dose chemotherapy with ASCT as initial treatment • Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2 • A participant must agree not to be pregnant, breastfeeding, or planning to become pregnant while enrolled in this study or within 6 months after the last dose of study treatment • A participant must agree not to plan to father a child while enrolled in this study or within 100 days after the last dose of study treatment
Critères d'exclusion	• Received any prior therapy for multiple myeloma or smoldering myeloma other than a short course of corticosteroids (not to exceed total of 160 milligrams [mg] dexamethasone or equivalent). In addition, received a cumulative dose of systemic corticosteroids equivalent to greater than or equals to (>=) 20 mg of dexamethasone within 14 days before randomization • Had plasmapheresis within 28 days of randomization • Had a stroke, transient ischemic attack, or seizure within 6 months prior to randomization • Known allergies, hypersensitivity, or intolerance to teclistamab or talquetamab excipients

- Known contraindications to the use of daratumumab or lenalidomide per local prescribing information
- Myeloma Frailty Index of >=2 with the exception of participants who have a score of 2 based on age alone