# Essai Clinique

Généré le 18 mars 2025 à partir de

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| Titre | A Phase 3 Randomized Study Comparing Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma Who Are Transplant Eligible |
| Protocole ID | CARTITUDE-6 |
| ClinicalTrials.gov ID | NCT05257083 |
| Type(s) de cancer | Myélome |
| Phase | Phase III |
| Type étude | Clinique |
| Médicament | Daratumumab, bortézomib, lénalidomide et Dexaméthasone (DVRd) suivi de Ciltacabtagène Autoleucel versus Daratumumab, bortézomib, lénalidomide et dexaméthasone (DVRd) suivi d'une greffe autologue de cellules souches |
| Institution | CHU DE QUEBEC – UNIVERSITE LAVAL<br>HOPITAL DE L'ENFANT-JESUS<br>1401 18e Rue, Québec, QC, G1J 1Z4 |
| Ville | |
| Investigateur principal | Dr Marc Lalancette |
| Coordonnateur | Philippe Nadeau<br>418-649-0252 poste 63115 |
| Statut | Actif en recrutement |
| Date d'activation | 01-08-2024 |
| But étude | The purpose of this study is to compare the efficacy of Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Ciltacabtagene Autoleucel versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) followed by Autologous Stem Cell Transplant (ASCT) in newly diagnosed multiple myeloma patients. |
| Critères d'éligibilité | • Participants with documented NDMM according to IMWG diagnostic criteria, for whom high-dose therapy and ASCT are part of the intended initial treatment plan.<br>• Measurable disease, as assessed by central laboratory, at screening as defined by any of the following:<br>  • Serum monoclonal paraprotein (M-protein) level ≥1.0 g/dL or urine M-protein level ≥200 mg/24 hours; or<br>  • Light chain MM without measurable disease in serum or urine: serum Ig free-light chain (FLC) ≥10 mg/dL and abnormal serum Ig kappa lambda FLC ratio.<br>• ECOG performance status of grade 0 or 1<br>• Clinical laboratory values within prespecified range. |
| Critères d'exclusion | • Prior treatment with CAR-T therapy directed at any target.<br>• Any prior BCMA target therapy.<br>• Any prior therapy for MM or smoldering myeloma other than a short course of corticosteroids<br>• Received a strong cytochrome P450 (CYP)3A4 inducer within 5 half-lives prior to randomization<br>• Received or plans to receive any live, attenuated vaccine (except for COVID-19 vaccines) within 4 weeks prior to randomization.<br>• Known active, or prior history of central nervous system (CNS) involvement or clinical signs of meningeal involvement of MM |

- Stroke or seizure within 6 months of signing Informed Consent Form (ICF)