

# Essai Clinique

Généré le 26 avr. 2025 à partir de

Titre	A Phase 3, Two-stage, Randomized, Multi-center, Controlled, Open-label Study Comparing Iberdomide Maintenance to Lenalidomide Maintenance Therapy After Autologous Stem Cell Transplantation (ASCT) in Participants With Newly Diagnosed Multiple Myeloma (NDMM)
Protocole ID	EXCALIBER-Maintenance
ClinicalTrials.gov ID	<a href="https://clinicaltrials.gov/ct2/show/study/NCT05827016">NCT05827016</a>
Type(s) de cancer	Myélome
Phase	Phase III
Type étude	Clinique
Médicament	Iberdomide en entretien versus Lenalidomide en entretien
Institution	CHU DE QUEBEC – UNIVERSITE LAVAL HOPITAL DE L'ENFANT-JESUS 1401 18e Rue, Québec, QC, G1J 1Z4
Ville	
Investigateur principal	Dr Marc Lalancette
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Statut	Actif en recrutement
Date d'activation	01-12-2023
But étude	The purpose of this study is to compare the effectiveness of iberdomide maintenance to lenalidomide maintenance therapy after autologous stem cell transplantation (ASCT) in participants with newly diagnosed multiple myeloma (NDMM).
Critères d'éligibilité	<ul style="list-style-type: none"> <li>Confirmed diagnosis of symptomatic multiple myeloma (MM)</li> <li>Eastern Cooperative Oncology Group performance status (ECOG) score of 0, 1, or 2</li> <li>Received 3 to 6 cycles of an induction therapy that includes a proteasome inhibitor (PI) and immunomodulatory (IMiD) [eg, bortezomib thalidomide and dexamethasone (VTd), lenalidomide, bortezomib and dexamethasone (RVd)] with or without a CD38 monoclonal antibody, or Velcade® (bortezomib), cyclophosphamide, dexamethasone (VCd), and followed by a single or tandem autologous stem cell transplantation (ASCT). Post-stem cell transplant consolidation is permitted</li> <li>Participants within 12 months from initiation of induction therapy who achieved at least a partial response (PR) after autologous stem cell transplantation (ASCT) with or without consolidation, according to International Myeloma Working Group (IMWG 2016) criteria</li> </ul>
Critères d'exclusion	<ul style="list-style-type: none"> <li>Progressive disease or clinical relapse (as defined by IMWG response criteria) following ASCT with or without consolidation or is not responsive to primary therapy</li> <li>Smoldering myeloma, solitary plasmacytoma or nonsecretory myeloma</li> <li>Known central nervous system/meningeal involvement of MM</li> <li>Prior history of malignancies, other than MM, unless the participant has been free of the disease for ≥ 5 years</li> </ul> <p>Other protocol-defined inclusion/exclusion criteria apply</p>