Essai Clinique

Généré le 05 mai 2024 à partir de

Titre	A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared With Pomalidomide and Dexamethasone in Subjects With t(11;14)-Positive Relapsed or Refractory Multiple Myeloma
Protocole ID	M13-494
ClinicalTrials.gov ID	NCT03539744
Type(s) de cancer	Myélome
Phase	Phase III
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Venetoclax et dexaméthasone comparé à pomalidomide et dexaméthasone
Institution	CISSS DE CHAUDIERE-APPALACHES HOTEL-DIEU DE LEVIS 143 rue Wolfe, Lévis, QC, G6V 3Z1
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Statut	Fermé
But étude	A study designed to evaluate the safety and efficacy of venetoclax plus dexamethasone (VenDex) compared with pomalidomide plus dexamethasone (PomDex) in participants with t(11;14)-positive Relapsed or Refractory Multiple Myeloma.
Critères d'éligibilité	• Documented diagnosis of multiple myeloma (MM) based on standard IMWG criteria. • Measurable disease at screening as defined per protocol. • Has received at least 2 prior lines of therapy as described in the protocol. • Has had documented disease progression on or within 60 days after completion of the last therapy. • Has received at least 2 consecutive cycles of lenalidomide and be relapsed/refractory to lenalidomide, as defined per protocol. • Has received at least 2 consecutive cycles of a proteasome inhibitor (PI). • Has MM positive for t(11;14). • An Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2. • Laboratory values (liver, kidney and hematology laboratory values) that meet criteria as described per protocol.
Critères d'exclusion	• History of treatment with venetoclax or another B-Cell Lymphoma (BCL)-2 inhibitor or pomalidomide. • History of other active malignancies, including myelodysplastic syndromes (MDS), within the past 3 years (exceptions described in the protocol). • Evidence of ongoing graft-versus-host disease (GvHD) if prior stem cell transplant (SCT). • Prior treatment with any of the following: allogeneic or syngeneic SCT within 16 weeks prior to randomization; or autologous SCT within 12 weeks prior to randomization. • Known central nervous system involvement of MM. • Concurrent conditions as listed in the protocol.