Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Modular Phase I/II, Open-label, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Lmmunogenicity, Pharmacodynamics, and Preliminary Efficacy of AZD0305 as Monotherapy or in Combination With Anticancer Agent(s) in Participants With Relapsed or Refractory Multiple Myeloma
Protocole ID	D7230C00001
ClinicalTrials.gov ID	NCT06106945
Type(s) de cancer	Myélome
Phase	Phase I-II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	AZD0305 en monothérapie ou en association avec d'autres agent anticancéreux
Institution	CENTRE UNIVERSITAIRE DE SANTE MCGILL SITE GLEN 1001 boul. Décarie , Montréal, QC, H4A 3J1
Ville	
Investigateur principal	Dr Chaim Shustik Dr Michael Sebag
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Statut	Actif en recrutement
But étude	This is a Phase I/II, modular, open-label, multicenter, dose escalation, and dose expansion/optimization study to evaluate the safety, tolerability, PK, immunogenicity, pharmacodynamics, and preliminary efficacy of AZD0305 in participants with RRMM.

Critères d'éligibilité	• Participants must be at least 18 years of age or the legal age of consent in the jurisdiction in which the study is taking place.
	• Eastern Cooperative Oncology group (ECOG) performance status of ≤ 2.
	• Documentation of Multiple Myeloma (MM) as defined by International Myeloma Working Group (IMWG) Diagnostic Criteria for Multiple Myeloma. Site should ensure that Multiple Myeloma diagnosis is confirmed in accordance with the IMWG Diagnostic Criteria.
	• Participants must have one or more of the following measurable disease criteria:
	  • Serum M-protein level ≥ 0.5 g/dL.
	  • Urine M-protein level ≥ 200 mg/24h.
	  • Serum immunoglobulin free light chain ≥ 10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio.
	• Adequate organ and bone marrow function assessment at screening according to the hematological, hepatic, and renal parameters listed in the CSP.
	• Participants must have received at least 3 prior lines of treatment which include a proteasome inhibitor (e.g., bortezomib), an immunomodulator (e.g., lenalidomide), and an anti-CD38 antibody (e.g., daratumumab).

Critères d'exclusion	• Participants exhibiting clinical signs of central nervous system involvement of MM. • Participants with known COPD, or previous history of ILD. • Participants with known moderate or severe persistent asthma within the past 5 years, or uncontrolled asthma of any classification. • Participants who have severe cardiovascular disease which is not adequately controlled. • Participants who have a history of immunodeficiency disease. • Participants with peripheral neuropathy ≥ Grade 2. • Primary refractory MM. • Participants who have previously received anti-GPRC5D or MMAE-containing treatment. • Participants who have previously received allogenic stem cell transplant, or participant has received autologous stem cell transplant within 3 months before the first dose of study intervention.