Essai Clinique

Généré le 03 mai 2024 à partir de

Titre	Étude multicentrique de phase 3, à répartition aléatoire, en double aveugle, contrôlée par placebo, visant à évaluer l'efficacité et l'innocuité du tafasitamab plus lénalidomide et rituximab par rapport au lénalidomide en plus du rituximab chez les patients atteints de LF de stade 1 à 3a ou de LZM
Protocole ID	InMIND (INCMOR 0208-301)
ClinicalTrials.gov ID	NCT04680052
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase III
Stade	Lymphome folliculaire/zone marginale
Type étude	Clinique
Médicament	Tafasitamab + Lénalidomide et Rituximab comparé à placebo + Lénalidomide et Rituximab
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	
Investigateur principal	Dre Isabelle Fleury
Coordonnateur	Nawel Mechtouf 514-252-3400 poste 4681
Statut	Actif en recrutement
But étude	This is a Phase 3 double-blind, placebo-controlled, randomized study designed to investigate whether tafasitamab and lenalidomide as an add-on to rituximab provides improved clinical benefit compared with lenalidomide as an add-on to rituximab in patients with R/R FL Grade 1 to 3a or R/R MZL.
Critères d'éligibilité	• Histologically confirmed Grade 1, 2, or 3a FL or nodal MZL, splenic MZL, or extra nodal MZL • Willingness to avoid pregnancy or fathering children • In the opinion of the investigator, be able and willing to receive adequate mandatory prophylaxis and/or therapy for thromboembolic events (eg, aspirin 70-325 mg daily or low-molecular-weight heparin) • Previously treated with at least 1 prior systemic anti-CD20 immunotherapy or chemo-immunotherapy • Documented relapsed, refractory, or PD after treatment with systemic therapy • ECOG performance status of 0 to 2
Critères d'exclusion	• Women who are pregnant or breastfeeding. • Any histology other than FL and MZL or clinical evidence of transformed lymphoma • Prior non-hematologic malignancy • Congestive heart failure • HCV positivity, chronic HBV infection or history of HIV infection • Active systemic infection • CNS lymphoma involvement • Any systemic anti-lymphoma and/or investigational therapy within 28 days prior to the start of Cycle 1 • Prior use of lenalidomide in combination with rituximab