Essai Clinique

Généré le 16 mai 2024 à partir de

Titre	A Phase 2, Open-label, Single Arm, Multicenter Trial to Evaluate the Safety and Efficacy of JCAR017 (Lisocabtagene Maraleucel) in Adult Subjects With High-risk, Relapsed or Refractory Indolent B-cell Non-Hodgkin Lymphoma (NHL)
Protocole ID	TRANSCEND FL
ClinicalTrials.gov ID	NCT04245839
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase II
Stade	Récidivant/réfractaire (2ième ligne de traitement et plus)
Type étude	Clinique
Médicament	Lisocabtagene Maraleucel
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	Olivier Cormier 514-252-3400 poste 5966
Statut	Actif en recrutement
But étude	This is a global Phase 2, open-label, single-arm, multicohort, multicenter study to evaluate efficacy and safety of JCAR017 in adult subjects with r/r FL or MZL. The study will be conducted in compliance with the International Council on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use/Good Clinical Practice (GCP) and applicable regulatory requirements. This study is divided into three periods: • Pretreatment, which consists of screening assessments, leukapheresis and the Pretreatment evaluation; • Treatment, which starts with the administration of lymphodepleting (LD) chemotherapy and continues through JCAR017 administration at Day 1 with follow-up through Day 29; • Posttreatment, which includes follow-up assessments for disease status and safety for 2 years.
Critères d'éligibilité	
Critères d'exclusion	