Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	Phase 1, Multicenter, Open-Label Study of the Antibody-Drug Conjugate TRPH-222 in Subjects With Relapsed and/or Refractory B-Cell Lymphoma
Protocole ID	TRPH-222-100
ClinicalTrials.gov ID	NCT03682796
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase I
Stade	Lymphome diffus à grandes cellules B
Type étude	Traitement
Médicament	TRPH-222
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dre Sarit Assouline
Coordonnateur	Chadi Zakaria 514-340-8222 poste 28326
Statut	Fermé
But étude	This is a Phase 1, multi-center, open-label study of TRPH-222 monotherapy in subjects with relapsed and/or refractory B-cell NHL. The study will be conducted in two Stages: Dose-Escalation, Dose-Expansion.
Critères d'éligibilité	• Age ≥ 18 years at the time of signing the informed consent • Histologically confirmed (2016 WHO lymphoma classification) B-cell NHL that is DLBCL, FL (including transformed FL), MZL, or MCL • Relapsed and/or refractory NHL requiring systemic therapy and have failed, are intolerant to, or are considered ineligible for standard of care anticancer treatments that are known to be potentially curative. Subjects must not be current candidates for HSCT. Participants who refuse standard treatments may also be considered provided that documentation is provided that the subject has been made aware of all therapeutic options • Eastern Cooperative Oncology Group (ECOG) status 0-2
Critères d'exclusion	• Presence of a leukemic phase of the lymphoma • "Double hit" or "triple hit" germinal center B cell lymphoma • Previous solid organ allograft (except for corneal transplant) • Peripheral neuropathy > NCI-CTCAE Grade 1 • Significant organ dysfunction that would preclude study participation • Significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias • Any other serious active disease or co-morbid medical condition, according to the Investigator's decision or Medical Monitor, that will substantially increase the risk associated with the subject's participation in the study