Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Étude de phase Ib sur l'utilisation du tisagenlecleucel en association avec le pembrolizumab dans le traitement du lymphome diffus à grandes cellules B (LDGCB) récidivant ou réfractaire (r/r)
Protocole ID	CCTL019J2101 (PORTIA)
ClinicalTrials.gov ID	NCT03630159
Type(s) de cancer	Lymphome non-hodgkinien (LNH)
Phase	Phase I
Stade	Récidive
Type étude	Traitement
Médicament	Tisagenlecleucel avec Pembrolizumab
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dre Isabelle Fleury
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Statut	Fermé
But étude	A multi-center, open-label, phase Ib study to evaluate the safety and efficacy of the administration of tisagenlecleucel in combination with pembrolizumab in patients with r/r DLBCL who have received 2 or more lines of systemic therapy, including an anti-CD20 and anthracycline based chemotherapy and having failed to or are not candidates for ASCT. The study will consist of 2 parts: dose timing selection part and expansion part.
Critères d'éligibilité	• Confirmed DLBCL per local histopathology assessment. • Relapsed or refractory disease after having recieved 2 or more lines of systemic therapy, including anti-CD20 and anthracycline based chemotherapy, and either having progressed after (or relapsed after) ASCT, or being not candidates for or not consenting to ASCT. • Measurable disease at time of enrollment • ECOG performance status that is either 0 or 1 at screening.
Critères d'exclusion	• Patients with Richter's transformation, and Burkitt lymphoma, and primary DLBCL of CNS. • Prior treatment with any prior anti-CD19/anti-CD3 therapy, or any other anti-CD19 therapy. • Patients with active CNS involvement are excluded, except if the CNS involvement has been effectively treated and provided that local treatment was >4 weeks before enrollment. • Prior allogeneic HSCT. • Unstable angina and/or myocardial infarction and/or coronary artery bypass graft (CABG), or stroke within 6 months prior to screening, and/or impaired cardiac function or clinically significant cardiac disease • Patients with a history of prior treatment with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibodies, other immune checkpoint inhibitors. • History of interstitial lung disease or (non-infectious) pneumonitis that required oral or intravenous steroids (other than COPD exacerbation) or current pneumonitis. Other protocol-defined inclusion/exclusion criteria may apply.