Essai Clinique

Généré le 09 mai 2025 à partir de

Titre	Master Protocol to Assess the Safety and Recommended Phase 2 Dose of Next Generations of Autologous Enhanced NY-ESO-1/ LAGE-1a TCR Engineered T-cells, Alone or in Combination With Other Agents, in Participants With Advanced Tumors
Protocole ID	209012
ClinicalTrials.gov ID	NCT04526509
Type(s) de cancer	Sarcome
Phase	Phase II
Stade	Maladie avancée ou métastatique
Type étude	Clinique
Médicament	GSK3901961 et GSK3845097
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	Dr Jonathan Noujaim
Coordonnateur	Olivier Cormier 514-252-3400 poste 5966
Statut	Fermé
But étude	New York esophageal antigen-1 (NY-ESO-1) and LAGE-1a antigens are tumor-associated proteins that have been found in several tumor types. Clinical trials using adoptively transferred T-cells directed against NY-ESO-1 have shown objective responses. GSK3901961 and GSK3845097 are next generation engineered TCR T-cells, co-expressing the CD8α cell surface receptor, targeting NY-ESO-1, and co-expressing the dnTGF-βRII cell surface receptor, targeting NY-ESO-1, respectively to potentially improve function. This is a master protocol evaluating first time in human T-cell therapies. It will initially consist of two independent substudies, investigating GSK3901961 and GSK3845097 in HLA*A02+ participants with NYESO1+ previously treated advanced (metastatic or unresectable) synovial sarcoma (SS) and/or previously treated metastatic non-small cell lung cancer (NSCLC).
Critères d'éligibilité	• Participant must be >=18 years of age on the day of signing informed consent. • Participant must be positive for Human leukocyte antigen (HLA)-A*02:01, HLA-A*02:05, and/or HLA-A*02:06 alleles • Participant's tumor is positive for NY-ESO-1 expression by a designated central laboratory. • Performance status: Eastern Cooperative Oncology Group of 0-1. • Participant must have adequate organ function and blood cell counts 7 days prior to leukapheresis. • Participant must have measurable disease according to RECIST v1.1 Additional criteria for participants with synovial sarcoma • Participant has advanced (metastatic or unresectable) synovial sarcoma confirmed by histology. • Participant has received/completed treatment with anthracycline or anthracycline with ifosfamide for advanced (metastatic or inoperable) disease and progressed. Additional criteria for participants with non-small cell lung cancer (NSCLC): • Participant has Stage IV NSCLC as confirmed by histology or cytology. • Participant has been previously treated with or is intolerant to programmed death receptor-1 (PD)-1/Programmed cell death ligand 1 (PD-L1) checkpoint blockade therapy and doublet taxane & platinum chemotherapy.

Critères d'exclusion	• Central nervous system metastases, except in rare cases of NSCLC as specified in the protocol. • Any other prior malignancy that is not in complete remission. • Clinically significant systemic illness. • Prior or active demyelinating disease. • History of chronic or recurrent (within the last year prior to leukapheresis) severe autoimmune or immune mediated disease requiring steroids or other immunosuppressive treatments. • Previous treatment with genetically engineered NY-ESO-1-specific T cells. • Previous NY-ESO-1 vaccine or NY-ESO-1 targeting antibody. • Prior gene therapy using an integrating vector. • Previous allogeneic hematopoietic stem cell transplant. • Washout periods for prior radiotherapy and systemic chemotherapy must be followed. • Major surgery <=28 days of first dose of study intervention. • For participants with NSCLC that harbors an actionable genetic aberration, e.g. BRAF, anaplastic lymphoma kinase (ALK)/ c-ros oncogene 1 (ROS1) or others, has received and failed >=3 lines of systemic therapy.