Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Evaluate Dostarlimab as Sequential Therapy After Chemoradiation in Participants With Locally Advanced Unresected Head and Neck Squamous Cell Carcinoma
Protocole ID	JADE
ClinicalTrials.gov ID	NCT06256588
Type(s) de cancer	ORL
Phase	Phase III
Type étude	Clinique
Médicament	Dostarlimab
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	
Investigateur principal	Dr Khashayar Esfahani
Coordonnateur	Chadi Zakaria 514-340-8222 poste 28326
Statut	Actif en recrutement
Date d'activation	07-05-2024
But étude	The goal of this study is to assess the safety and effectiveness of Dostarlimab compared to Placebo in adult participants with HNSCC (Head and Neck Squamous Cell Carcinoma)

Critères d'éligibilité	Participants are eligible to be included in the study only if all of the following criteria apply:
	• Has newly diagnosed unresected LA histologically confirmed HNSCC of the oral cavity, oropharynx, hypopharynx or larynx and completed cisplatin plus radiotherapy (termed "CRT" in this protocol) with curative intent and has no evidence of distant metastatic disease.
	• Has provided acceptable core or excisional tissue demonstrating:
	  • PD-L1 positive tumor status
	  • If the primary tumor site is oropharyngeal carcinoma, the participant must have p16 IHC testing.
	• Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
	• Has adequate organ function.

Critères d'exclusion	Participants are excluded from the study if any of the following criteria apply: • Has received prior radiation therapy, systemic therapy, targeted therapy, or radical surgery for management of head and neck cancer not considered part of CRT. • Has cancer outside of the oropharynx, larynx, hypopharynx or oral cavity, such as nasopharyngeal, sinus, other para-nasal, or other unknown primary head and neck cancer. • Has undergone any major surgical procedure or experienced significant traumatic injury within 28 days prior to enrolment. • Has any history of interstitial lung disease or pneumonitis (past or current). • Has cirrhosis or current unstable liver biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal/gastric varices, or persistent jaundice. • Has a history or current evidence of any medical condition, therapy, or laboratory abnormality that might confound the study results, interfere with their participation for the full duration of the

study intervention, or indicate it is not in the best interest of the participant to participate, in the opinion of the investigator.

- Is receiving any other anticancer or experimental therapy. No other experimental therapies (including but not limited to chemotherapy, radiation, hormonal treatment, antibody therapy, immunotherapy, gene therapy, vaccine therapy, or other experimental drugs) of any kind are permitted while the participant is receiving study intervention.
- Previous treatment with anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or an agent directed to another stimulatory or coinhibitory T-cell receptor [e.g., Cytotoxic T-lymphocyte associated protein 4 (CTLA4), OX-40, CD137]
- Is pregnant, breastfeeding, or expecting to conceive children within the projected duration of the study, starting with the Screening Visit through 120 days after the last dose of study intervention.
- Has a history of severe allergic and/or anaphylactic reactions to chimeric, human or humanized antibodies, fusion proteins, or known allergies to dostarlimab or its excipients.