Essai Clinique

Généré le 18 mars 2025 à partir de

Titre	A Phase 3 Randomized, Double-blind, Multicenter, Global Study of Monalizumab or Placebo in Combination With Cetuximab in Participants With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck Previously Treated With an Immune Checkpoint Inhibitor
Protocole ID	INTERLINK-1
ClinicalTrials.gov ID	NCT04590963
Type(s) de cancer	ORL
Phase	Phase III
Type étude	Clinique
Médicament	Monalizumab ou placebo en association avec cétuximab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
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Investigateur principal	Dr Khashayar Esfahani
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Statut	Actif en recrutement
But étude	This is a randomized, double-blind, multicenter, global Phase 3 study to assess the efficacy and safety of monalizumab and cetuximab, compared to placebo and cetuximab, in patients with recurrent or metastatic head and neck cancer.
Critères d'éligibilité	• Are aged 18 years and over • Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN), (oral cavity, oropharynx, hypopharynx, or larynx) which has progressed on or after previous systemic cancer therapy and is not amenable to curative therapy • Received prior treatment using a PD-(L)1 inhibitor • Prior platinum failure • Received 1 or 2 prior systemic regimens for recurrent or metastatic SCCHN • Has measurable disease per RECIST 1.1 • A fresh or recently acquired tumor tissue for the purpose of biomarker testing • World Health Organization (WHO)/ Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
Critères d'exclusion	• Head and neck cancer of any primary anatomic location in the head and neck not specified in the inclusion criteria, including participants with SCCHN of unknown primary or non-squamous histologies • Had prior cetuximab therapy (unless it was administered in curative locally advanced setting with radiotherapy and no disease progression for at least 6 months following the last cetuximab dose) • Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease [eg, colitis or Crohn's disease], diverticulitis • Any concurrent anticancer treatment, except for hormonal therapy for non-cancer-related conditions (eg, hormone replacement therapy)