Essai Clinique

Généré le 07 mai 2024 à partir de

Titre	A Phase 2 Non-randomized, Open-label, Multi-cohort, Multi-center Study Assessing the Clinical Benefit of SAR444245 (THOR-707) Combined With Other Anticancer Therapies for the Treatment of Participants With Head and Neck Squamous Cell Carcinoma (HNSCC)
Protocole ID	ACT16903
ClinicalTrials.gov ID	NCT05061420
Type(s) de cancer	ORL
Phase	Phase II
Type étude	Clinique
Médicament	SAR444245 avec pembrolizumab, SAR444245 + pembrolizumab et cétuximab, SAR444245 avec cétuximab
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Ville	
Investigateur principal	Dr Nathaniel Bouganim
Coordonnateur	
Statut	Actif en recrutement
Date d'activation	19-07-2022
But étude	This is a phase 2 multi-cohort, non-randomized, open-label, multi-center study assessing the clinical benefit of SAR444245 combined with other anticancer therapies for the treatment of participants aged 18 years and older with HNSCC. This study is structured as a master protocol for the investigation of SAR444245 with other anticancer therapies**Substudy 1-Cohort A1** aims to establish proof-of-concept that SAR444245 combined with the anti-PD1 antibody pembrolizumab, will result in a significant increase in the observed number of objective responses in trial participants with HNSCC who are treatment-naïve for recurrent and/or metastatic (R/M) disease.**Substudy 2 - Cohort A2** aims to establish proof-of-concept that SAR444245 combined with both the anti-PD1 antibody pembrolizumab and cetuximab will result in a significant increase in the observed number of objective responses in trial participants with HNSCC who are treatment-naïve for recurrent and/or metastatic (R/M) disease **Substudy 4-Cohort B1** aims to establish proof-of-concept that SAR444245 combined with the anti-PD1 antibody pembrolizumab, will result in a significant increase in the observed number of objective responses in trial participants with HNSCC who have received treatment with PD1/PD-L1 and platinum-based regimen**Substudy 5-Cohort B2** aims to establish proof-of-concept that SAR444245 combined with cetuximab will result in a significant increase in the observed number of objective responses in trial participants with HNSCC previously treated with platinum-based regimen & cetuximab-naïve after failure of no more than 2 regimens for recurrent and/or metastatic (R/M) disease.
Critères d'éligibilité	• Participants must be ≥ 18 years of age inclusive, at the time of signing the informed consent . • Histologically or cytologically confirmed diagnosis of R/M HNSCC that is considered not amenable to further therapy with curative intent. The eligible primary tumor locations are oropharynx, oral cavity, hypopharynx, and larynx (nasopharynx is excluded). • Measurable disease. • Baseline biopsy must be submitted for all cohort A1, A2 Core Phase participants. • Baseline biopsy must be submitted for all cohort B1, B2 Expansion Phase participants Known HPV p16 status for oropharyngeal cancer. • Participant agrees to follow protocol-specified contraception guidelines.

Critères d'exclusion	• Eastern Cooperative Oncology Group (ECOG) performance status of ≥2. • Has received prior IL2-based anticancer treatment. • For participants in Cohorts A1, A2: --Prior treatment with an agent (approved or investigational) that blocks the PD-1/PD-L1 pathway (participants who joined a study with an anti-PD-1/PD-L1 in the experimental arm but have written confirmation they have not received anti-PD-1/PD-L1 are allowed). • For participants in Cohorts A2, B2: --Prior treatment with cetuximab (prior cetuximab allowed if used for the treatment of locally advanced disease, with no progressive disease for at least 4 months from completion of prior cetuximab therapy). • For participants in Cohorts A2, B2: --Electrolytes (magnesium, calcium, potassium) outside the normal ranges. • Participants under anti-hypertensive treatment who cannot temporarily (for at least 36 hours) withhold antihypertensive medications prior to each IMP dosing. • Participants with baseline SpO2 ≤92% (without oxygen therapy). • Comorbidity requiring corticosteroid therapy (>10 mg prednisone/day or equivalent) within 2 weeks of IMP initiation. Inhaled or topical steroids are permitted, provided that they are not for treatment of an autoimmune disorder. Participants who require a brief course of steroids (eg, as prophylaxis for imaging studies due to hypersensitivity to contrast agents) are not excluded. The above information is not intended to contain all considerations relevant to a patient's potential participation in a clinical trial.