

# INCAGN01876 in Combination With Immunotherapy in Participants With Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

**Status:** Recruiting

## Eligibility Criteria

**Age:** 18 years to 99 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

- Histologically or cytologically confirmed recurrent or metastatic HNSCC (oral cavity, oropharynx, hypopharynx, or larynx), that is not amenable to local therapy with curative intent (surgery or radiation therapy with or without chemotherapy). Participants with squamous cell carcinomas of the nasopharynx, salivary gland, or nonsquamous cell histology are excluded.
- Documented progression on or after PD-(L)1 inhibitor alone or in combination with platinum-based chemotherapy for recurrent or metastatic HNSCC. Exception: Treatment Group B (Part 2, expansion): PD-(L)1-naïve.
- ECOG performance status of 0 to 1.
- Measurable disease based on RECIST v1.1.
- Mandatory pre-treatment and on-treatment tumor biopsies.
- GTR-positive tumor confirmed by central laboratory before study treatment start.
- Willingness to avoid pregnancy or fathering children.

### Exclusion Criteria:

- Have received chemotherapy, targeted small molecule therapy or curative radiation within 21 days of first dose of study drug; prior mAB for anticancer therapy other within 28 days of first dose of study drug; or investigational study drugs or devices within 28 days or five half-lives prior to enrollment unless approved by medical monitor.
- Prior treatment with any TNF Super Family agonist therapy.
- Have not recovered to  $\leq$  Grade 1 from toxic effects of prior therapy.
- Laboratory and medical history parameters not within the Protocol-defined range before the first administration of study treatment. Known active HBV or HCV, or Known to be seropositive for HIV.
- Have an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids, or immunosuppressive drugs).
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- Known active infections requiring systemic treatment.

## Conditions & Interventions

### Interventions:

Biological: INCAGN01876, Biological: retifanlimab

### Conditions:

Recurrent Cancer, Metastatic Cancer, Advanced Malignancies, Head and Neck Squamous Cell Carcinoma

### Keywords:

carcinoma, carcinoma, squamous cell, squamous cell carcinoma of head and neck, anti-PD-(L)1 therapy, HNSCC, SCCHN

## More Information

**Contact(s):** Incyte Corporation Medical Information (US and Canada) Call Center (US) - medinfo@incyte.com

**Principal Investigator:**

**Phase:** Phase 2

**IRB**

**Number:**

**System ID:** NCT05359692

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