



## A Randomized, Double-blind, Adaptive, Phase II/III Study of GSK3359609 or Placebo in Combination with Pembrolizumab for First-Line Treatment of PD-L1 Positive Recur-rent/Metastatic Head and Neck Squamous Cell Carcinoma

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The study will evaluate the efficacy of GSK3359609 in combination with pembrolizumab compared with pem-brolizumab plus placebo as a standard first-line chemo-therapy-free regimen in HNSCC. All participants will be stratified by 2 factors i) PD-L1 CPS status (CPS  $\geq 20$  vs.  $1 \leq$  CPS  $< 20$ ); ii) HPV status in oropharyngeal cancers (positive vs. negative/unknown) vs non-oropharyngeal cancers then randomly assigned in a 1:1 ratio to the GSK3359609/ pembrolizumab arm or pembrolizumab/placebo arm.

**keywords**

GSK3359609, Placebo in Combination with Pembrolizumab, First-Line Treatment of PD-L1 Positive Recur-rent/Metastatic, Head and Neck Squamous Cell Carcinoma

**type of project**

clinical studies

**status**

ongoing - recruiting phase

**start of project**

2020

**end of project**

2021

**study design**

Phase II

**responsible person**

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